Government of Canada
Gouvernement du Canada

A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Table of Contents

Acknowledgements

Preface

Executive Summary

1. The Current Domestic and International Human Rights Framework

2. Assisted Human Reproduction

3. Pre-Implantation Genetic Diagnosis

4. A Right to Research

5. Human Rights Issues Related to Genetic Information and Privacy

6. Human Rights and Patenting

7. Biotechnology, Rights and Traditional Knowledge

Conclusion

Glossary

106-03426/

Acknowledgements

The authors would like to take this opportunity to thank the many individuals cited below who contributed to the writing of this document. We would like to begin with a special thank you to Glenn Rivard for initiating the project, recognizing its value for those departments involved in biotechnology, and to Elisabeth Eid for accepting responsibility for the project. Also, special thanks are due the Canadian Biotechnology Secretariat, especially John Olsthoorn, for their enthusiasm and support, and for providing the necessary funding for the project. Without their financial support, the project would not have gone ahead.

Each chapter of the document was reviewed by leading Canadian academics. We are grateful to the following individuals for their careful review and extensive comments: Dr. Francoise Baylis, Professor John Borrows, Professor Timothy Caulfield, Professor Jocelyn Downie, Professor Richard Gold, Professor Bartha Knoppers, and Professor Jennifer Llewellyn.

Support staff at the Human Rights Law Section assisted us in many ways. We would like to especially thank Sue Lévis who edited, fixed footnotes, and formatted the entire document, and Tracey Demeter, Rachel Perreault and Josée Ménard for their help.

We were fortunate to have a steering committee for the project, whose members reviewed chapters and provided feedback. We would like to thank Sylvia Batt, Ruth Barr, Geneviève Clavel, Angela Arnet Connidis, Nancy De Clerq, Elisabeth Eid, Suzanne Fortin, Valerie Howe, Raymond MacCallum, Elaine Menard, Glenn Rivard and Rob Sutherland-Brown.

The authors would like to thank the following colleagues in the Human Rights Law Section for taking the time to review various chapters and provide their invaluable comments: Elisabeth Eid, Raymond MacCallum, Julia Dryer, Laura Farquharson and Jane Arbour. In addition, we would like to thank the following counsel at various departmental Legal Services Units for their review and comments: Anahita Ariya-Far, Andre Dorion, Shela Larmour, Jane Northey, and Theresa Siok.

Last, but not least, we would like to thank Rodney Ghali, Senior Policy Advisor, Health Canada, for reviewing three of the chapters for scientific accuracy. To us, he will always be the "Science Guy."

Preface

This first phase of the two-year Biotechnology and Human Rights Framework Project began in July, 2003, with the document completed in May 2004. The work entailed many hours of research, reflecting, consulting, writing and revising.

The intent of the first phase was to thoroughly examine the current, and in some cases the future, applications of certain applications of biotechnology to determine whether they raised any human rights issues. Where they did, the current human rights framework was examined to determine whether it adequately addressed the issues or whether there was a gap.

The chapter on genetic information and privacy (Chapter 5) summarizes and builds upon the work of the Genetic Information and Privacy Working Group, which had already done extensive research and consultations in this area. The authors examined other areas of biotechnology, including assisted human reproduction, pre-implantation genetic diagnosis, scientific research, patenting of human genes and tissues, and indigenous knowledge and human rights. Time constraints meant that we were unable to examine all the applications of biotechnology. For example, we were unable to examine whether genetically modified organisms raised any human rights issues. This issue is important and should be examined in the not too distant future.

The second phase of the Project will explore in more depth the gaps identified in the first phase and proposes various policy and legislative measures to address the gaps. In addition, consultations will be undertaken with the departments and Legal Service Units ("LSUs") affected by the gaps to discuss the findings and proposed solutions. The ultimate goal is to support the government's objective of enhancing public confidence and awareness by demonstrating that human rights issues will form an essential part of the governance of biotechnology.

Executive Summary

The term "biotechnology" has been defined in the *Canadian Environmental Protection Act* as:

> *...the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.*[1]

It has been predicted that in this century advances in biotechnology will result in more changes in the lives of individuals and in society than those wrought by telecommunications and computers in the last. Even prior to the year 2000, biotechnology affected the food Canadians grew and ate, the fuels they used as energy sources, the drugs they consumed, the medical therapies used to combat disease, and human reproduction. In the 21st century, we are witnessing applications of biotechnology that previously only existed in the realm of science fiction, such as the cloning of human embryos.

As with all technological advances, biotechnology can result in benefits and drawbacks for society. It might be argued, however, that biotechnology raises special concerns and considerations because it involves the manipulation and alteration of natural biological materials and processes. This is especially true in the case of assisted human reproduction ("AHR") and patented inventions using or incorporating human biological materials, such as genetic and cellular therapies.

The ability to fertilize a human egg with sperm outside the body of a woman (*in vitro*) has led to increased knowledge about the embryo and how it develops. It has also led to reproduction and research possibilities that would not have been contemplated even a few years ago.

The technology of AHR makes it possible for a child today to have more than two "parents." A child could have two biological parents who donated sperm and an egg for reproductive purposes. An infertile couple (the social parents) could arrange to use the donated sperm and egg to create an *in vitro* embryo for reproduction. If the social mother was physically unable to bear a child, the couple might arrange for the *in vitro* embryo to be transferred into the body of a surrogate mother to develop and grow. Once the child is born, the surrogate mother would relinquish custody of the child to the social parents. In this example, the child would have two biological parents, two social parents and one surrogate mother, for a total of five parents.

The application of biotechnology raises ethical, moral and novel legal issues, which are discussed in the following chapters. The authors adopted a forward-looking approach to biotechnology and canvassed a wide variety of perspectives and viewpoints in order to fully canvass the human rights issues.

Each chapter examines the application of a particular biotechnology and whether the application raises any human rights issues. International, regional and domestic sources of human rights are examined for each issue.

Chapter 1 provides an overview of the relevant international and regional human rights instruments, and explains how these instruments are used by domestic courts in defining human rights in Canada. Chapter 1 also includes a brief overview of the sources of human rights in Canada. For example, the *Canadian Charter of Rights and Freedoms* ("*Charter*") is discussed and references made to the most relevant provisions. In addition, the first chapter discusses positive rights, which impose obligations on the state to take a particular action to assist a person to exercise the right, and negative rights, which impose a duty on the state not to interfere with a person's exercise of that right. Important human rights concepts are also discussed in the chapter, such as human dignity and equality.

---

[1] *Canadian Environmental Protection Act*, 1999, c.33, s. 3(1).

The next two chapters (Chapters 2 and 3) deal with applications of biotechnology in the area of AHR. Each chapter describes the science, identifies the human rights issues, and sets out the relevant provisions in international and regional instruments, as well as the provisions in the *Charter* and any applicable Canadian legislation. The law in other jurisdictions is examined and academic commentary provided to illustrate the different perspectives and viewpoints on each issue. This is followed by a discussion and a conclusion, which highlights any gaps in the current human rights framework.

Chapter 2 examines the human rights issues that arise when biotechnology is applied to assist with human reproduction. The ability to create *in vitro* human embryos in a dish in the lab has enabled many infertile individuals and couples to reproduce. This chapter examines whether there is a positive obligation on the state to fund AHR services and concludes that at the present time there is no such obligation. The chapter also examines whether persons have a negative right to access AHR services free from state interference. If the state limited access to services on the basis of marital status, sexual orientation, or age, human rights would clearly be implicated. In such a case, the equality rights under s. 15 of the *Charter* would be engaged.

Chapter 2 also examines the rights of children and donors with respect to the disclosure of personal information. Do children have a right to the personal information, including the identity, of the donor whose reproductive material was used in their creation? Rights under international instruments, such as the *Convention on the Rights of the Child*, and the *Charter* are examined. It is clear that the interests of children, born as a result of AHR, to personal information about their genetic parent (donor), and the interests of the donors of reproductive material to privacy are inter-related and have the potential to conflict. This would make it difficult for the courts to determine whose rights take precedence.

What is the status of the *in vitro* embryo, existing as it does outside the body of a woman? Does the *in vitro* embryo have any rights? These questions are also explored in Chapter 2. At the current time, the common law does not consider either the *in vitro* or the *in utero* embryo to be a human being with legal or human rights. The chapter also examines whose rights would control the disposition of stored *in vitro* embryos in the event of a dispute between the progenitors. American jurisprudence has held that the constitutionally protected right to reproductive autonomy, flowing from the right to liberty, contains two equal but opposite rights, the right to procreate and the right **not** to procreate. In the event of a dispute as to embryo disposition, courts in the United States have developed a legal formula in which the right not to procreate is assigned slightly more weight. It is likely that the courts in Canada would find a similar *Charter*-protected right to reproductive autonomy within the liberty interest in section 7, but whether the Canadian courts would adopt a similar approach to settling a private disposition dispute is not clear. The *Charter* would not apply to a dispute between purely private parties. However, the courts may look to the *Charter* and common law as sources of public policy, with respect to reproductive autonomy, especially the right not to reproduce, in order to dispose of any agreement or contract and to inform a decision as to disposition.

Chapter 3 examines pre-implantation genetic diagnosis ("PGD") of the *in vitro* embryo. PGD permits the detection of the *in vitro* embryo's sex, as well as the presence of a chromosomal or genetic anomaly that may be indicative of a genetic disease or disorder, such as Huntington's disease. The worldwide use of PGD is on the rise and is controversial. Some people fear its widespread use signals a return to the eugenics movement of the early 20th century, and others worry that its use to detect the sex of the embryo may lead to a disruption in the natural male/female birth ratio in society.

Do parents have a human right to access information, without state interference, about the genetic status of their *in vitro* embryos, especially when the parents are at risk of passing on a serious genetic disease? Women in Canada have a constitutionally protected right to make decisions free from state interference during the early stages of pregnancy and are free to access a variety of medical procedures, such as amnioscentesis, to discover the genetic status of an *in utero* embryo.

Are a woman's rights any different when the embryo is *in vitro* instead of *in utero*? Assuming that the liberty interest in section 7 ofthe *Charter* protects a right to reproductive autonomy, how broad is that right in Canada? It is likely that the liberty interest would be found to protect a woman's right to make decisions of fundamental personal importance, without state interference, in the area of assisted reproduction. A decision to access PGD to select and transfer to a woman's body only those *in vitro* embryos that are free of a particular genetic disease or disorder would arguably qualify as such a decision. The courts would likely find that any state action prohibiting access to PGD would at least engage a person's section 7 *Charter* rights.

Would the human right to reproductive autonomy be broad enough to allow prospective parents to access PGD to select and transfer *in vitro* embryos based on other characteristics, such as the embryo's sex and the presence or absence of genes indicating disability? For example, if both parents are deaf, they may wish to have a deaf child. Do they have a right to use PGD to select only those *in vitro* embryos that have the gene for deafness? The courts may question whether such information is essential or material to a decision to reproduce, such that access to that information deserves constitutional protection. Women currently are free to access this information once they are pregnant and they are free to undergo an abortion based on that information. In the case of PGD, however, the embryo exists outside the woman's body. Does the embryo's *in vitro* existence affect the woman's right to reproductive autonomy? Another related question may be whether the woman has a right to all the information about the *in vitro* embryo, including its sex and other characteristics, prior to giving a free and informed consent to its transfer into her body.

Chapter 3 also examines whether the *in vitro* embryo has a human right to be born with a sound body and mind. American jurisprudence in some states has held that children have a legal right to be born with a sound body and mind, and have allowed tort claims by the child based on "wrongful life." Furthermore, some states allow children to sue for preconception torts, i.e., for negligent acts before conception that have resulted in an injury. Is it possible that the courts might at some point determine that the *in vitro* embryo, existing as it does outside the body of a woman, has human rights? Arguably, its existence outside the body of a woman means that there is no conflict with the liberty and security of the person rights of the woman. However, at least for the foreseeable future, the *in vitro* embryo must be transferred into a woman's body to realize its potential for human life, and to develop and grow to the point of viability. The courts in Canada have not been asked whether such a right exists under the *Charter* and predicting the outcome of such a question is highly speculative. The current situation may represent a gap in human rights protection.

It is important to note that despite the fact that state actions may be found to engage certain rights under section 7 of the *Charter*, the onus remains on the claimant to establish that the state's deprivation of the right was not in accordance with the principles of fundamental justice. If the state's deprivation was found not to be in accordance with the principles of fundamental justice, it is unlikely that the state would be asked to justify the violation, under section 1 of the *Charter*, since a violation would have already been made out and the courts consider it unlikely that the state would be able to provide an adequate justification. With respect to the other rights in the *Charter*, the state would have an opportunity to argue that the violation represents a justified limitation in a free and democratic society under section 1. If the state is successful, the violation would be found to be constitutionally valid.

Research is the focus of Chapter 4. Do scientific researchers have a right to engage in research or scientific inquiry? Would the *Charter* right to freedom of thought, belief, opinion and expression in section 2(b) protect a researcher's right to experiment? Chapter 4 examines this question in the context of research using stem cells derived from therapeutically cloned *in vitro* embryos. This research is believed to hold much promise for developing medical cures and therapies for many degenerative human diseases, such as Alzheimer's, spinal cord injuries, and juvenile-onset diabetes. Furthermore, one day these stem cells may be used to grow replacement tissues and organs that would not be rejected by the recipient's body.

At the level of international human rights instruments, provisions advocating a right to undertake scientific research are generally balanced by provisions allowing the state to interfere with such a right in the interests of health, safety, *ordre public* and public morality. It is likely that a state restriction against scientific research would be found by the courts to engage a researcher's right to freedom of thought, belief, opinion and expression in section 2(b) of the *Charter*. The state would have the opportunity to justify any limitation or restriction on the researcher's rights under section 1 of the *Charter* and if successful, the limitation would be found to be constitutionally valid.

Advances in biotechnology have resulted in a significant increase in our knowledge of the human embryo and embryonic development. The last issue in chapter 4 examines whether the method or the purpose of creation has any affect on the moral status of the *in vitro* embryo. For most individuals, the use of an *in vitro* embryo in research that results in its destruction raises moral and ethical concerns. When *in vitro* embryos are created for research purposes and have little or no potential for human life, would the moral and ethical concerns be diminished? Five sources of *in vitro* embryos are discussed to determine whether differences in potentiality and purpose affect the moral status of the embryo.

The human rights issues related to genetic information and privacy are discussed in Chapter 5. Genetic information has taken on increased importance since the mapping of the human genome. Scientists are discovering the genes responsible for many genetic diseases and disorders. Genetic information about an individual is personal information and can be obtained through a family history or through genetic testing. The chapter focuses on two issues related to genetic information: discrimination and privacy.

Chapter 5 examines discrimination in the employment and insurance context. It concludes that although no statutory prohibition exists against discrimination on the basis of a genetic predisposition to disease, recent jurisprudence suggests that it would be caught under the rubric of disability. The *LaForest Report* recommended that the definition of disability in federal human rights legislation be amended to include genetic predisposition to illness.

Privacy encompasses the liberty and integrity interests of individuals. Privacy is closely related to confidentiality. Chapter 5 examines privacy in the context of whether a right to know or not know exists with respect to genetic information. The *Charter* is an important source of protection for privacy in Canada, as well as federal and provincial privacy legislation and the common law.

Although the *Charter* does not provide a specific right to privacy, sections 7 and 8 encompass privacy interests. As with any *Charter*-protected right or interest, it is not absolute. In the case of sections 7 and 8, the courts undertake a limited balancing of the competing interests at stake. In addition, the state may limit a right or interest as long as the limitation can be justified under section 1 of the *Charter*. The chapter concludes that there does not appear to be a legal right in Canada to know the genetic information of a close family member or to be informed of whether one is at risk of developing a genetic disease on the basis of a close family member's test results. In Canada, a person's genetic information would be protected under constitutional and privacy law, and unauthorized disclosures may result in legal action.

Chapter 6 explores patents and human rights. It begins with a brief history of patents and an explanation of the science relating to patents in the area of biotechnology. The chapter examines whether individuals have property rights in their body, including their excised bodily materials. The common law is examined, including the pivotal American case of *Moore v. The Regents of the University of California*, along with statutory provisions that grant limited property rights in the human body, as well as the principle of human dignity. Recent Supreme Court of Canada decisions regarding patentability, scope and infringement are reviewed.

This chapter explores, with the assistance of hypothetical scenarios, whether the patenting of human biological materials, such as a single human cell, raises any human rights issues. Based on the hypothetical examples, one is able to conclude that the patenting of human materials may raise human rights norms and values, specifically liberty and security of the person. However, the analysis illustrates that it is not always possible to determine with certainty whether patenting engages human rights under the *Charter*. In those hypotheticals where there is no government action implicated, it is possible to conclude that the *Charter* will not apply. This is the case where the deprivation occurs as a result of the actions of a patentee who is a private entity. However, in other situations where the patentee is a government department or agency, or where the courts issue an injunction, on the basis of the *Patent Act*, the answer is less clear.

Chapter 6 also examines whether the patenting of a human single-celled or pronuclear *in vitro* embryo raises any human rights interests or issues. There are some regional instruments, such as the European Parliament's *Directive*, that prohibit the patenting of *in vitro* embryos that are used for industrial or commercial purposes, and some foreign jurisdictions that consider the embryo as a human being from the moment of conception. In some of these jurisdictions, the human embryo is assigned legal rights. In the state of Louisiana, for example, the *Civil Code* protects the *in vitro* embryo and deems it a juridical person who can sue and be sued.

Both the majority and dissenting opinions of the Supreme Court in *Harvard Mouse* noted in *obiter* that a fertilized mouse egg[2] would be patentable subject matter under the *Patent Act*. If the human pronuclear *in vitro* embryo was found to be patentable subject matter under the Act, it would raise moral and ethical concerns for many individuals. The inability to exclude certain subject matters from patentability under the *Patent Act* may represent a gap in legislative protection.

Chapter 7 examines indigenous traditional knowledge and human rights. This chapter is divided into two parts. The first part articulates wording for a possible indigenous right to use and control traditional knowledge after examining statements of several indigenous groups. The second part of the chapter examines the existence of such a right at the international level and the domestic level.

The chapter's introduction describes traditional knowledge, as well as its connection to "rights." For indigenous peoples, traditional knowledge is intimately connected with the land, culture and language. Traditional knowledge is something owned by the indigenous community, as a community "asset" to be shared and used for the benefit of the members and not "private property" held and controlled by an individual member. This view of "natural resources" and "knowledge" is contrary to the view reflected by the legal regimes internationally and in Canada, which tend to favour the promotion of innovation in biotechnology research by rewarding creators and inventors through, for example, a system of patents. In the past, indigenous peoples willingly shared their special knowledge of the natural world only to have it used for the commercial gain of others. This knowledge was often used without the consent of indigenous communities, by researchers engaged in bioprospecting or so-called "bio-piracy," to gain access to valuable genetic or biological resources.

The chapter explores whether a right to traditional knowledge exists at the international level. Despite the fact that no international instrument provides indigenous peoples with a right to control traditional knowledge, "rights talk" respecting traditional knowledge has been recently finding its way into the decisions of international bodies, such as the *Conference of the Parties* under the *Convention on Biological Diversity*. Developments internationally provide guidance to States regarding the utilization of traditional knowledge in ways that respect the concerns and interests of indigenous peoples.

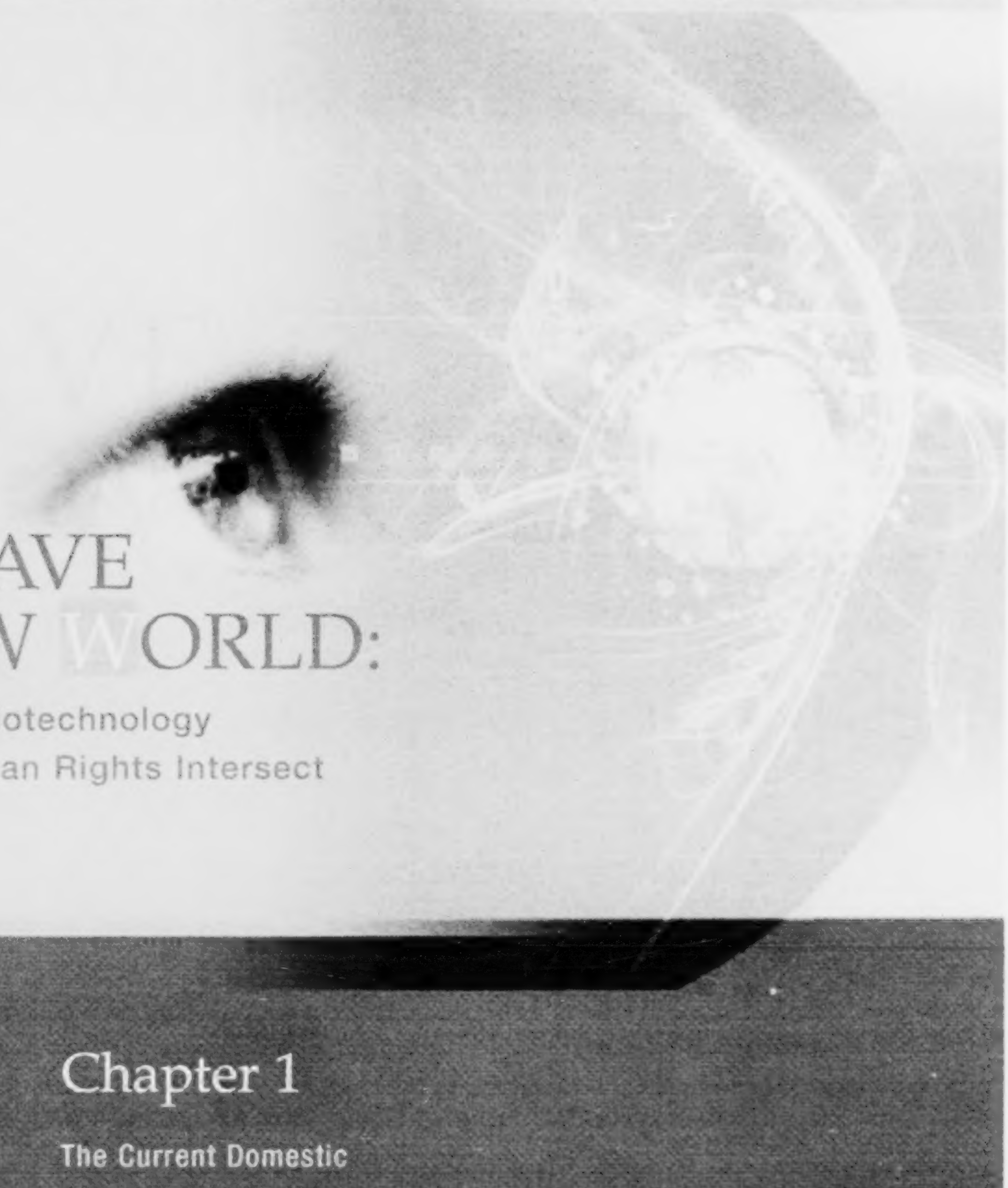
The chapter also examines the possible existence of a basis in Canadian law for an assertion that Aboriginal peoples have a right to own and control their traditional knowledge. Traditional knowledge has not yet been the specific subject of "aboriginal rights" litigation. It is, however, relevant to land claims and self-government negotiations and has been addressed in bilateral agreements between Aboriginal communities and resource development companies or researchers. Since it has not itself been the subject of litigation, comments about the relationship between traditional knowledge and aboriginal rights jurisprudence are highly speculative. General conclusions about the existence or non-existence of rights to traditional knowledge under Canadian law therefore cannot be drawn. Although there is no case law in Canada confirming an Aboriginal right respecting traditional knowledge, the approach taken in jurisprudence to date could be used to inform efforts to address indigenous peoples' concerns respecting the use of traditional knowledge.

---

[2] Patent Office practice in Canada is to patent only single cell organisms. The majority opinion in *Harvard Mouse* was that there was no reason to alter the line drawn by the Patent Office regarding the patentability of life forms. Given that Patent Office practice is to patent only single cell organisms, it may be reasonable to conclude that the Court's comment with respect to the patentability of a fertilized mouse egg was to a single-celled mouse embryo.

Chapter 7 concludes with a brief overview of some options that could be used to respect, preserve and maintain traditional knowledge, such as intellectual property laws or *sui generis* laws and policies. Viewing traditional knowledge through the lens of "rights" raises the issue of balancing. The rights of the Aboriginal community must be balanced against the rights of the broader society to knowledge that may carry with it significant social benefits. The chapter ends by proposing that domestic and international experience suggests that a key element in any effort to find ways to address concerns about the misuse of traditional knowledge would include giving indigenous people opportunities to play a central role in law and policy making about issues such as traditional knowledge in biotechnology research.

Government of Canada Gouvernement du Canada



A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 1

The Current Domestic and International Human Rights Framework

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 1

Table of Contents

1.1 Introduction 1–1

1.2 Human Rights Law in Canada 1–1

1.3 International Human Rights Law 1–3

1.4 Relationship between Domestic and International Human Rights Law 1–4

1.5 Human Rights and Relevant Concepts 1–4

1.6 Conclusion 1–8

Chapter 1

The Current Domestic and International Human Rights Framework

Elisabeth Eid and Katherine van Heugten

1.1 Introduction

The objective of this paper is to identify and analyze human rights issues relating to biotechnology within the current human rights framework and to identify areas where the current human rights framework does not adequately address the issues. Therefore, it is essential to have a general understanding of domestic and international human rights law and existing and evolving human rights concepts. The following is an overview of the major human rights instruments and concepts that will be considered throughout this paper.

1.2 Human Rights Law in Canada

In Canada, the main domestic sources of human rights law are the *Canadian Charter of Rights and Freedoms* ("*Charter*"),[1] the *Canadian Bill of Rights* ("*CBR*")[2] and human rights legislation.[3]

Canadian Charter of Rights and Freedoms

For the purpose of identifying and analyzing human rights issues related to biotechnology, the most significant source of human rights law in Canada is the *Charter*. It outlines the fundamental rights and freedoms that are constitutionally guaranteed to individuals in Canada. With respect to the biotechnology applications discussed in this paper, the most relevant rights and freedoms include: the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice;[4] the right to be secure from unreasonable search and seizure;[5] and equality rights.[6]

The *Charter* does not apply to all types of activities. Pursuant to section 32(1), the application of the *Charter* is limited to Parliament and the federal government with respect to all matters within federal authority, as well as the governments and legislatures of the provinces and territories with respect to all matters within their jurisdiction. The *Charter* does not apply to purely private action.

Further, the rights and freedoms set out in the *Charter* are not absolute. Rather, they are guaranteed under section 1, "subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society."[7] The courts have developed a multi-step test for justification under section 1 of the *Charter* whereby the government must demonstrate that the objective of the statute or government action in question is pressing and substantial; that the infringement is rationally connected to the objective; that it impairs the right or freedom at issue as little as possible and that the infringement's effect is proportional to the objective.[8]

---

[1] Part I of the *Constitution Act 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11.

[2] S.C. 1960, c. 44.

[3] See for example at the federal level, the *Canadian Human Rights Act*, R.S.C. 1985, c. H-6. Provinces and territories have comparable human rights legislation.

[4] *Supra* note 1 at s. 7.

[5] *Ibid.* at s. 8.

[6] *Ibid.* at s. 15(1).

[7] *Ibid.* at s. 1.

[8] This test was originally set out in *R. v. Oakes*, [1986] 1 S.C.R. 103 and was refined in *Egan v. Canada*, [1995] 2 S.C.R. 513. The third part of the test was reformulated in *Dagenais v. Canadian Broadcast Corp.*, [1994] 3 S.C.R. 835.

A key question surrounding the rights expressed in the *Charter* is the extent to which they impose positive obligations on the government. This question is particularly relevant to the 'right to health' debate. The existence of a positive right, which could translate into a positive obligation upon the state, suggests a duty to support the right claimed by taking positive measures. A negative right, in general terms, simply requires the government not to interfere with the right.[9]

However, it should be noted that this positive versus negative distinction is not clearly demarcated and often breaks down upon further analysis. Some traditionally negative obligations may require the positive expenditures of funds by the government. For example, the government incurs substantial costs to respect the right to a fair trial, which is traditionally viewed as a negative right.

The reluctance or willingness of the courts to impose positive obligations on the government has been varied. For example, in *Dunmore v. Ontario*,[10] the Supreme Court of Canada ("SCC") imposed a positive obligation on the government of Ontario to protect the freedom of association rights of a group of agricultural workers pursuant to section 2(d) of the *Charter*. In *G.(J). v. New Brunswick (Minister of Health and Community Services)*,[11] the SCC found that the government had an obligation under section 7 of the *Charter* to provide funded legal counsel under certain circumstances in child wardship proceedings. In the health care context, a positive obligation was imposed directly or indirectly on the government pursuant to section 15 of the *Charter* in both *Eldridge v. British Columbia (Attorney General)*[12] *and Auton (Guardian ad litem of) v. British Columbia (Minister of Health)*,[13] which are discussed in detail in the following chapter.

In contrast, the SCC found that section 7 of the *Charter* did not impose a positive obligation on the state to provide adequate living standards to individuals in *Gosselin v. Quebec*.[14] The majority of the Court examined the relevant jurisprudence and found that it did not suggest section 7 placed positive obligations on the state. Rather, section 7 has been interpreted as restricting the state's ability to deprive individuals of their right to life, liberty and security of the person.

Underscoring this positive versus negative rights dynamic is the debate surrounding the appropriate balance between the courts and elected branches of government. The central question being: to what extent should the courts interpret the *Charter* so as to impose positive obligations on the government that would effectively interfere with public policy choices or compel financial allocation?

Canadian Bill of Rights ("CBR")

The *CBR* is a "quasi-constitutional" federal statute that only applies to federal legislation. If a federal law cannot be construed or applied consistently with the *CBR*, the *CBR* will override it, unless the federal law explicitly states otherwise.[15] The rights and freedoms set out in the *CBR* are similar to those found in the *Charter*, which has for all practical purposes largely displaced the *CBR*. The most notable differences are the protection of property rights in the *CBR*,[16] which were specifically excluded from protection under the *Charter* and the right to a fair hearing in s.2(e) of the *CBR*.

Human Rights Legislation

Human rights legislation exists at both the federal and provincial levels. The *Canadian Human Rights Act*[17] is very similar to provincial human rights legislation, which principally prohibits discriminatory practices based on listed grounds of discrimination, including disability or handicap.[18] The application of human rights legislation is different than that of the *Charter*, as generally, the former applies to both government and private actions, albeit within particular contexts, such as discrimination in employment, accommodation or services. The protections set out in these statutes will be specifically addressed in Chapter 5 — Genetic Information and Privacy in the context of discrimination based on a genetic characteristic.

---

[9] T. Friesen, "The Right to Health Care" (2001) 9 Health L. J. 205.

[10] [2001] 3 S.C.R. 1016.

[11] [1999] 3 S.C.R. 46.

[12] [1997] 3 S.C.R. 624.

[13] [2002] B.C.J. No. 2258 (B.C.C.A.) leave to S.C.C. granted [2002] S.C.C.A. No. 510.

[14] [2002] S.C.J. No. 85.

[15] *R. v. Drybones*, [1970] 2 S.C.R. 574 at 579; *Hogan v. The Queen*, [1975] 2 S.C.R. 574 at 584; *Singh v. Minister of Employment and Immigration*, [1985] 1 S.C.R. 177 at 238.

[16] *Supra* note 2 at s. 1(a).

[17] *Supra* note 3.

[18] *Supra* note 3

1.3 International Human Rights Law

Four sources of international law exist: (1) conventions or treaties; (2) customary international law; (3) general principles of law; and (4) judicial decisions and scholarly writings.[19] Of these four, it is generally agreed that the two primary sources of international law are conventions or treaties and customary international law. Conventions or treaties are binding agreements that define particular obligations of states that are parties to them, while customary international law is universally binding on states and arises from widespread state conduct that is believed to be legally required (*"opinio juris"*).[20]

A secondary source of international law is the body of law known as 'soft law'. The term 'soft law' is used to refer to such instruments as draft treaties, declarations and resolutions. Rather than being formal sources of law having legally binding force, these instruments are seen as evidence of state practice, which may translate over time into emerging international norms.[21] In most cases, the subject matter of such instruments is not thoroughly developed or agreed upon such as to allow for transformation into a treaty.[22] This body of principles or instruments is particularly significant to the identification and analysis of human rights issues related to biotechnology, given that biotechnology is a relatively new topic on the international stage.

One of the most significant steps towards moving human rights law to the forefront of international law was the inclusion post WWII of the protection of human rights as one of the purposes of the United Nations, followed by the adoption of the International Bill of Rights.

The following three documents are often referred to as the International Bill of Rights: (1) *Universal Declaration of Human Rights*,[23] [hereinafter *UDHR*]; (2) *International Covenant on Civil and Political Rights*,[24] [hereinafter *ICCPR*] and (3) *International Covenant on Economic, Social and Cultural Rights*,[25] [hereinafter *ICESCR*].

Although the *UDHR* is a declaration, and therefore not technically binding, it is generally accepted that many of the provisions in it have risen to the status of customary international law. Most of the rights outlined in the *UDHR* were later codified in the *ICCPR* and the *ICESCR*. The *ICCPR* includes provisions relating to the right to life, privacy, religion, expression, a fair trial and political participation. These rights are often referred to as first-generation rights, which protect individuals from state interference.

The *ICESCR* includes provisions relating to work, trade unions, social security, standard of living, health, family and education, etc. In accordance with the Covenant, these rights are to be progressively realized in light of available resources. Many of the rights outlined in the *ICESCR* are referred to as second-generation rights, which impose positive duties on states. However, some can be characterized as first-generation rights.

Canada is party to the *ICCPR* and the *ICESCR* as well as the main other human rights treaties including the *Convention on the Rights of the Child* and the *Convention on the Elimination of All Forms of Discrimination against Women*. Treaty bodies, usually referred to as "Committees", have been established pursuant to the various human rights treaties with mandates to monitor state compliance with the obligations under the treaties. Probably the best known example is the UN Human Rights Committee established to monitor the *International Covenant on Civil and Political Rights*. Other examples include the Committee on the Rights of the Child and the Committee on the Elimination of Discrimination against Women.

The primary role of these bodies is to review domestic implementation by those states that are party to the treaty through examining periodic national reports and with respect to some treaties, rendering opinions on individual complaints. The bodies may also produce "General Comments" which serve to interpret the provisions of the treaty and clarify state obligations pursuant to the treaty.

---

[19] Article 38, *Statute of the International Court of Justice*, 26 June 1945, Can. T.S. 1945 No. 7 (entered into force 24 October 1945); J.H. Currie, *Public International Law* (Toronto: Irwin Law Inc., 2001) at 80.

[20] Currie, *ibid.* at 84.

[21] *Ibid.* at 99.

[22] A. Aust, *Modern Treaty Law and Practice* (Cambridge: Cambridge University Press, 2000) at 44.

[23] GA Res. 217 (III) UN GOAR, 3rd Sess., Supp. No. 13, UN Doc. A/810 (1948)

[24] 16 December 1966, 999 U.N.T.S. 171 (entered into force 23 March 1976)

[25] 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976)

The views of the Committees and their "General Comments" are not binding on states but can carry considerable persuasive force.

Canada is also a member of the Organization of American States and by virtue of this membership, subject to the *American Declaration on the Rights and Duties of Man*. Individuals may submit complaints to the Inter-American Commission on Human Rights alleging violations by Canada of the Declaration. The decisions of the Commission on such complaints are not binding on Canada but have considerable persuasive force. Decisions of the Commission on provisions of the Declaration serve as an important source of interpretation of the provisions of the instrument.

Canada is not a member of the Council of Europe but has observer status with the organization. Canada is not party to the human rights treaties adopted by the Council of Europe and thus they are not binding on Canada. However, such instruments and how they have been interpreted may be of interest in informing interpretations of the *Canadian Charter of Rights and Freedoms*, as well as domestic legislation.

1.4 Relationship between Domestic and International Human Rights Law

In Canada, treaties are not self-executing. Rather, in order to have direct legal force at the domestic level, treaty obligations must be incorporated through enacting legislation by either the federal or provincial legislatures, depending on which has jurisdictional competence over the subject matter of the treaty obligation.[26] Human rights treaties are generally ratified on the basis of existing domestic legislation and policies rather than through incorporating legislation.

Although unincorporated human rights treaties may not form the basis of an action in domestic courts, they can be an important source of interpretation for both constitutional and ordinary legislation. For example, in relation to *Charter* rights, the SCC has stated that international obligations may inform the interpretation of the content of *Charter* rights.[27] Moreover, the SCC stated in *Baker v. Canada (Minister of Citizenship and Immigration)*[28] that the values reflected in international human rights law may help inform the contextual approach to statutory interpretation and judicial review of administrative action.

Given the important role human rights treaties may play in interpreting *Charter* rights and freedoms, as well as ordinary legislation, such treaties will be considered in relation to the human rights issues raised by biotechnology.

1.5 Human Rights and Relevant Concepts

Human Dignity

There is no right to human dignity; rather it is considered a human rights concept. The concept of human dignity occupies a central legal, moral and ethical role in modern human rights law. It appears in the preambles of all three instruments that comprise the *International Bill of Rights*. The preamble to the *UDHR* refers to the "dignity and worth of the human person,"[29] while the preambles to the *ICCPR* and the *ICESCR* note that human rights "derive from the inherent dignity of the human person."[30]

Traditionally, human dignity was identified as the foundation from which other human rights flowed and not as a right as such.[31] However, in recent years at the international level, violations of human dignity have increasingly been relied upon as a legal and moral basis unto itself.[32] This is most evident in recent biomedicine instruments. For example, in UNESCO's *Universal Declaration on the Human Genome and Human Rights*,[33] human dignity appears in several articles of the Declaration and plays a central role in defining and regulating the human genome.

---

[26] Currie, *supra* note 19 at 205.

[27] Dunmore, *supra* note 10; *Granovsky v. Canada* (Minister of Employment and Immigration) [2001] 1 S.C.R. 703; *United States v. Burns*, [2001] 1 S.C.R. 283; *Suresh v. Canada* (Minister of Citizenship and Immigration), [2002] 1 S.C.R. 3.

[28] [1999] 2 S.C.R. 817.

[29] *UDHR*, *supra* note 23.

[30] *ICCPR*, *supra* note 24; ICESCR, supra note 25.

[31] Law Reform Commission of Canada, *Human Dignity and Genetic Heritage* (Study Paper) (Ottawa: Law Reform Commission of Canada, 1991) at 24.

[32] D. Bell, "Human Cloning and International Human Rights Law" (1999) 21 Sydney Law Review 202.

[33] *Universal Declaration on the Human Genome and Human Rights*, 1997, G.A. Res. 53/152, 53rd Sess. (1998).

Human dignity is also a key part of the Council of Europe's *Convention for the Protection of Human Rights and Dignity of the Human Being* with regard to the Application of Biology and Medicine.[34] In the Explanatory Report accompanying the Convention, it states that human dignity is the "essential value to be upheld"[35] and that all provisions in the Convention must be interpreted bearing in mind the goal is to protect human rights and dignity.[36] Moreover, the Explanatory Report states that respect for human dignity is central to the provisions respecting scientific research,[37] consent to research[38] and the provision respecting the sanctity of the human body.[39]

The term 'human dignity' does not appear in the *Charter*. However, human dignity is a fundamental value that underlies and informs human rights norms found within the *Charter*, particularly the rights enunciated in sections 2, 7, 8 and 15.[40] In fact, human dignity plays a central role in the equality analysis formulated by the SCC. The SCC elaborated on its conception of human dignity, particularly in the context of equality, in *Law v. Canada*,[41] where the Court stated:

> What is human dignity? There can be different conceptions of what human dignity means. For the purpose of analysis under s. 15(1) of the *Charter*, however, the jurisprudence of this Court reflects a specific, albeit non-exhaustive, definition…the equality guarantee in s. 15(1) is concerned with the realization of personal autonomy and self-determination. Human dignity means that an individual or group feels self-respected and self-worth. It is concerned with physical and psychological integrity and empowerment. Human dignity is harmed by unfair treatment premised upon personal traits or circumstances which do not relate to individual needs, capacities or merits. It is enhanced by laws which are sensitive to the needs, capacities and merits of different individuals, taking into account the context underlying their differences. Human dignity is harmed when individuals and groups are marginalized, ignored, or devalued, and is enhanced when laws recognize the full place of all individuals and groups within Canadian society.[42]

Privacy

At its earliest form, privacy was described as "the right to be let alone."[43] The cornerstones of the modern understanding of privacy are individual dignity and autonomy.[44]

The right to privacy is referred to in a number of international human rights instruments. Both the *UDHR* and the *ICCPR* contain similar provisions protecting against arbitrary interference with one's "privacy, family, home or correspondence" and against "attacks upon honour and reputation."[45] There is also a provision in the *Convention on the Rights of the Child* granting similar rights to children.[46]

There is no specific provision in the *Charter* guaranteeing an explicit "right to privacy". However, the SCC has interpreted the *Charter* to include privacy protections. With respect to section 8 of the *Charter*, the SCC has interpreted the right to be free from unreasonable search and seizure in a broad fashion "to secure the citizen's right to a reasonable expectation of privacy against governmental encroachments."[47] Further, the SCC has noted that privacy is "grounded in man's physical and moral autonomy" and is "essential for the well-being of the individual."[48]

---

[34] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, 4 April 1997, E.T.S. No. 164 (entered into force 1 December 1999).

[35] Council of Europe, *Explanatory Report to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (DIR/JUR (97) 1) (Strasbourg: Directorate of Legal Affairs, January 1997) at para. 9.

[36] *Ibid.* at para 22.

[37] *Supra* note 35 at Article 15.

[38] *Ibid.* at Article 17.

[39] *Ibid.* at Article 21.

[40] *Supra* note 28 at 33.

[41] [1999] 1 S.C.R. 497.

[42] *Ibid.* at para 53.

[43] S.D. Warren & L.D. Brandeis, "The Right to Privacy" (1890) 4 Harv. L. Rev. 193 at 193.

[44] See *Schreiber v. Canada (Attorney General)*, [1998] 1 S.C.R. 841 at para. 19; *R. v. Mills*, [1999] 3 S.C.R. 668. See also: M. Marshall & B. von Tigerstrom, "Health Information" in J. Downie, T. Caulfield & C. Flood (eds.), *Canadian Health Law and Policy* (2nd Ed.) (Markham: Butterworths, 2002); P.S. Florencio & E.D. Ramanathan, "Secret Code: The Need for Enhanced Privacy Protections in the United States and Canada to Prevent Employment Discrimination Based on Genetic and Health Information" (2001) 39 Osgoode Hall L.J. 77.

[45] UDHR, *supra* note 23 Article 12; ICCPR, supra note 24 at Article 17.

[46] *Convention on the Rights of the Child*, 20 November 1989, 1577 U.N.T.S. 3 (entered into force 2 September 1990) at Article 16.

[47] *R. v. Dyment*, [1988] 2 S.C.R. 417 at 426.

[48] *Ibid.* at 427-438.

With respect to section 7 of the *Charter* (right to life, liberty and security of the person), the SCC has found that it includes a residual right to privacy. Although, the Court has not made a precise determination as to whether the right to privacy emanates from the liberty component or the security of the person component of section 7. In some cases, the Court has relied on the liberty interest to protect an individual's right to privacy, whereas in others, the Court has relied on the security of the person component.[49] Further, the SCC has not clearly determined the interaction of the privacy interests under sections 7 and 8.[50]

The SCC has discussed three different categories of claims to privacy: (1) territorial or property privacy, such as the right to privacy in one's home; (2) personal privacy, such as the right to be free from bodily intrusions; and (3) informational privacy, which includes the right to control personal information about oneself.[51]

Other sources of privacy protections include the federal *Privacy Act*,[52] which governs the collection, use and disclosure of personal information by federal institutions, the *Personal Information Protection and Electronic Documents Act*,[53] which governs the collection, use and disclosure of personal information by federal public bodies, and by private sector bodies in the course of a commercial activity. In addition, there is provincial legislation respecting privacy,[54] which governs information held by provincial public bodies.

Liberty and Security of the Person

Although they are distinct rights, the right to liberty and the right to security of the person are often found together in a single provision. For example, the right to liberty and the right to security of the person are found together in article 3 of the *UDHR* and article 9 of the *ICCPR*.

Section 7 of the *Charter* guarantees "the right to life, liberty and security of the person, and the right not to be deprived thereof except in accordance with fundamental justice."

The liberty interest in section 7 contains two separate aspects. First, the right to liberty protects an individual's physical liberty. Individuals have a right to be free of physical restraint, such as imprisonment or extradition.[55] To constitute a deprivation of liberty, the physical restraint need not be severe.[56] Second, the liberty interest in section 7 provides a protected sphere in which individuals may make fundamental personal decisions, without state interference, that go to the essence of enjoying individual dignity.[57] However, not all personal decisions will be protected. The SCC has stated that the personal autonomy that stems from the liberty aspect of section 7 is not "synonymous with unconstrained freedom."[58]

The right to security of the person contained in section 7 of the *Charter* has been broadly interpreted. It includes the right to physical integrity, i.e., to control one's bodily integrity. The right will be engaged where state action interferes with the personal autonomy of an individual.[59] Security of the person has both a physical and psychological aspect, such that an individual's security of the person will be engaged where state action imposes physical punishment and/or causes severe psychological harm.[60] Not all state-imposed psychological harm will constitute a breach of one's security of the person.

---

[49] See *R. v. O'Connor*, [1995] 4 S.C.R. 411 at para. 487, where L'Heureux Dube J. concluded that the right to privacy was a significant aspect of the right to liberty in a free and democratic society; *R. v. Beare*, [1988] 2 S.C.R. 387 at 412, where LaForest J., writing for the Court, suggested that s. 7 included a right to privacy; *R. v. Morgentaler*, [1988] 1 S.C.R. 30, where the Court discussed the relationship between s. 7 and privacy and where Wilson J. stated that the liberty component of s. 7 included a right to make fundamental private decisions; *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519, where the Court held that the security of the person component of s. 7 protected the privacy of individuals with respect to decisions that affected their body.

[50] See *Lavallee, Rackel & Heintz v. Canada (Attorney General)*, [2002] S.C.J. No. 61; *Ruby v. Canada (Attorney General)*, [2002] S.C.J. No. 73.

[51] *Ibid.* at 429-430.

[52] R.S.C. (1985) c. P-21.

[53] S.C. 2000, c. 5.

[54] *Supra* note 53.

[55] *R. v. Vaillancourt*, [1987] 2 S.C.R. 636; *Kindler v. Canada (Minister of Justice)*, [1991] 2 S.C.R. 779.

[56] Compelling an individual to give oral testimony or fingerprints has been found to be deprivations of liberty. See *Thomson Newspapers Ltd. v. Canada (Director of Investigation & Research)*, [1990] 1 S.C.R. 425; *R. v. Beare*, *supra* note 49.

[57] *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307.

[58] *Ibid.* at para. 54.

[59] *Rodriguez*, *supra* note 49.

[60] Blencoe, *ibid.*; *G.(J.)*, *supra* note 11; *Winnipeg Child and Family Services v. K.L.W.*, [2000] 2 S.C.R. 519.

Rather, the harm must have a serious and profound effect on the individual's psychological integrity: it must be greater than ordinary stress or anxiety[61] but does not have to rise to the level of psychiatric illness.

The analysis under section 7 occurs in two stages. The courts would first determine whether a *Charter* right has been engaged by government action and then determine whether the deprivation was in accordance with the principles of fundamental justice. The courts must find that the government action deprived an individual of one or more of the interests in section 7, i.e., life, liberty or security of the person. Second, the courts would identify the relevant principle of fundamental justice in the circumstances of the case and would then determine whether the deprivation of the right was in accordance with the principles of fundamental justice.

The principles of fundamental justice are found in the basic tenets of the legal system, including, the common law, the rights set out in sections 8-14 of the *Charter* and international norms. There are both substantive and procedural principles of fundamental justice. They are legal principles that are in the domain of the judiciary and not the domain of public policy. There must be significant societal consensus that the principle is fundamental to the way in which the legal system ought fairly to operate and the principle must be able to be identified with sufficient precision to make it a standard against which a deprivation can be measured.

If the government deprivation is found to be in accordance with the principles of fundamental justice, then no *Charter* violation would have been made out. If, on the other hand, the deprivation is found not to have been in accordance with the principles of fundamental justice, then a *Charter* violation would have occurred. The courts might require the Crown to justify the violation under section 1 of the *Charter* as a reasonable limit in a free and democratic society. The onus is on the complainant during the first two stages of inquiry and on the Crown during the third stage, i.e., government justification under section 1.

Equality

The concept of equality is difficult to define in exact terms. A determination of whether there is a violation of the right to equality necessitates comparisons between individuals or groups. Defining the correct comparator group has been the subject of significant debate particularly concerning the appropriate comparisons and about what constitutes equal treatment.[62]

Equality guarantees appear in several international human rights instruments. Both the *UDHR*[63] and the *ICCPR*[64] contain equality provisions. In addition, international human rights instruments exist that specifically address discrimination against woman[65] and discrimination on the basis of race.[66]

The equality guarantee in section 15(1) of the *Charter* states that every individual has the right to equal benefit of the law without discrimination on the basis of enumerated or analogous grounds. Equality guarantees are also set out in the *Canadian Human Rights Act* and provincial human rights instruments, which typically relate more specifically to discrimination in the context of employment, accommodation or services.

The approach to be taken respecting discrimination claims under the *Charter* was set out by the SCC in *Law v. Canada (Minister of Employment and Immigration)*.[67] The claimant must prove: that the law imposes differential treatment between the claimant and others, in purpose or effect, on the basis of a personal characteristic; that the differential treatment is based on an enumerated or analogous ground; and that the treatment constitutes discrimination in a substantive sense, having the effect of treating the claimant as less worthy of concern, respect and consideration in a manner that offends human dignity.

---

[61] *G.(J.)*, *supra* note 11.

[62] R.J. Sharpe, K.E. Swinton & K. Roach, *The Charter of Rights and Freedoms*, 2nd ed. (Toronto: Irwin Law Inc., 2002) at 245.

[63] UHDR, *supra* note 23 at Articles 2, 7.

[64] ICCPR, *supra* note 24 at Articles 2, 26.

[65] *International Convention on the Elimination of All Forms of Discrimination Against Woman*, 18 December 1979, 1249 U.N.T.S. 13 (entered into force 3 September 1981).

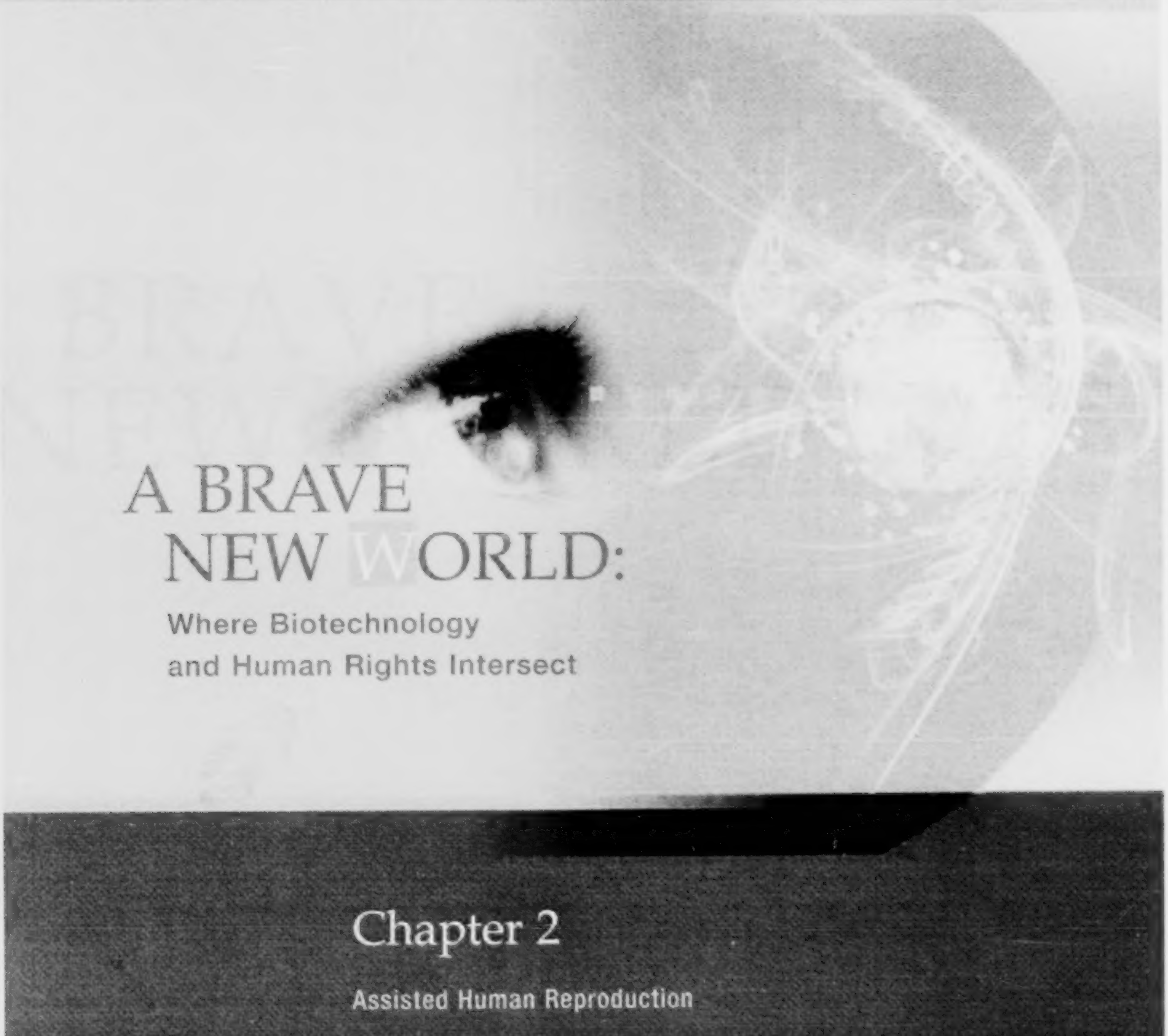
[66] *International Convention on the Elimination of All Forms of Racial Discrimination*, 7 March 1966, 660 U.N.T.S. 195 (entered into force 4 January 1969).

[67] [1999] 1 S.C.R. 497 at para. 39.

1.6 Conclusion

The foregoing discussion briefly outlined the major human rights instruments and concepts that will be considered throughout this paper in order to provide a general understanding of the current human rights framework. Each of the following chapters will examine this framework in greater detail as it relates to specific aspects of biotechnology. Each chapter will identify relevant human rights issues and address those areas where the current human rights framework does not adequately address the human rights issues raised by biotechnology.

Government of Canada
Gouvernement du Canada



A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 2

Assisted Human Reproduction

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 2

Table of Contents

2.1 Introduction 2–1

2.2 Background 2–2

2.2.1 The Science 2–2
2.2.2 The Canadian Context 2–2
2.2.3 The Comparative Context 2–4

2.3 Human Rights Issues Related to AHR 2–4

2.4 Issue 1: Access to AHR Services 2–4

2.4.1 The Right to Reproductive Autonomy 2–6
2.4.2 The Right to Health 2–9
2.4.3 The Right to Benefit from Scientific Progress 2–14
2.4.4 Conclusion 2–15

2.5 Issue 2: Access to and Disclosure of Information and the Implications for Offspring and Donors of Reproductive Material 2–16

2.5.1 The Situation in Canada 2–16
2.5.2 The Situation in Other Countries 2–16
2.5.3 Arguments For and Against the Disclosure of Donor Information 2–17
2.5.4 Children Born as a Result of Donated Reproductive Material and the Right to Know One's Genetic Heritage 2–18
2.5.5 Donors of Human Reproductive Material and the Right to Privacy 2–24
2.5.6 Conclusion 2–26

2.6 Issue 3: The Status of *In vitro* Embryos 2–27

2.6.1 The Rights of Donors of Reproductive Material and Recipient Couples vis-à-vis a Frozen *In vitro* Embryo 2–27
2.6.2 The Legal Status of the *In vitro* Embryo 2–29

2.7 Further Issues to Consider 2–39

2.8 Conclusion 2–39

Chapter 2

Assisted Human Reproduction

Katherine van Heugten and Judy Hunter

2.1 Introduction

> *More than any other scientific advancement, from the smallpox vaccine to the artificial heart, the techniques of medically assisted conception inspire an ongoing public debate on what attitude to adopt concerning these new powers over human reproduction.*[1]

In the later part of the last century, scientific advances made it possible to separate the fertilization of an ovum with sperm from the act of sexual intercourse. These advances were, and still are, important given that infertility affects a significant portion of our society. A recent estimate suggests that eight to twelve percent of couples suffer from some form of infertility.[2]

Assisted human reproduction ("AHR") has provided those individuals or couples, who would not otherwise be able to conceive a child through intercourse, or who are unable to carry a child to term, with options to create a family using their own genetic material or the genetic material of a donor. AHR has also provided those who can conceive naturally, but who are at risk of passing on a genetic disorder, the opportunity to avoid this risk. However, these new technologies have not developed without criticism. AHR has raised many profound legal, ethical and social issues ranging from health concerns surrounding the short- and long-term effects of fertility interventions, to concerns respecting the commercialization of life and the resulting impact on human dignity.

Given the large number of issues surrounding AHR, two chapters will be dedicated to the subject. Chapter 2 will identify and discuss human rights issues related to AHR generally, while chapter 3 will identify and discuss the human rights issues that arise from the application of AHR technologies to the *in vitro* embryo, such as pre-implantation genetic diagnosis, research involving *in vitro* embryos and somatic cell nuclear transfer (cloning for reproductive purposes).

Each chapter will describe the science involved, as well as the Canadian and international human rights contexts. Thereafter, the various human rights issues will be identified and analyzed within the existing domestic and international frameworks and, where appropriate, within a comparative contexts. Finally, gaps in the current domestic legislative and policy framework will be identified.

This paper will examine the international and comparative legal frameworks prior to the Canadian legal framework, as the former has the potential to inform the interpretation of Canadian law. Furthermore, the rapidly evolving nature of the subject matter and the lack of human rights discourse in relation to AHR in Canada compelled the authors to draw on other areas of the law, such as contract and tort law, to inform the human rights analysis.

---

[1] B.M. Knoppers & S. LeBris, "Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues" (1991) 17 Am. J. L. and Med. 329.

[2] R. Cook, B. Dickens & M. Fathalla, *Reproductive Health and Human Rights* (Oxford: Oxford University Press, 2003) at 11. See also Health Canada http://www.hc-sc.gc.ca/english/media/releases/2002/2002_34bk4.htm (date accessed: February 13, 2004).

2.2 Background

2.2.1 The Science

The term AHR encompasses many activities, including, therapeutic insemination ("TI"), *in vitro* fertilization ("IVF"), gamete intra-fallopian transfer ("GIFT") and intra-cytoplasmic sperm injection ("ICSI").

Therapeutic Insemination

Therapeutic insemination includes both artificial insemination ("AI") and donor insemination ("DI"). TI, whether using sperm from a husband, partner, known or anonymous donor is a simple procedure that uses a syringe to place sperm into a woman's vagina.

Medical indications for DI include azoospermia (absence of living sperm in the male partner's semen), oligospermia (scarcity of sperm in the male partner's semen) or the presence of a genetic disease in the male partner's sperm. Women who would like an offspring, but who do not have a male partner, may also use DI.

In Canada, donor sperm is available from sperm banks or fertility clinics. Donors are carefully screened and all donated sperm must be quarantined and must undergo comprehensive testing.[3]

***In vitro* Fertilization**

IVF is a multi-step procedure that involves the stimulation of a woman's ovaries using hormonal treatment in order to produce a number of eggs, the surgical retrieval of eggs from the ovaries, fertilization of the mature eggs with sperm in a Petri dish, and transfer of the resulting embryo(s) into a woman's uterus. Usually, no more than four embryos are transferred per cycle. If there are more embryos available that are required for transfer, these embryos may be cryopreserved or 'frozen' for later use.[4] If these embryos are not later used for reproductive purposes, they may be discarded, donated to another individual or couple, or donated for research use.

IVF is used where the male has poor sperm function or a low sperm count, where the woman's fallopian tubes are blocked or when a risk of passing on a genetic disorder exists.

IVF has been in use since 1978 when the world's first 'test-tube' baby, Louise Brown, was born in the United Kingdom ("U.K."). It is estimated that since 1978, approximately 1 million babies have been born worldwide using IVF.[5]

Gamete Intra-Fallopian Transfer

In GIFT, egg retrieval is accomplished in the same way as in IVF. However, after retrieval, the eggs and sperm are injected into the fallopian tube to allow fertilization to occur in vivo, as opposed to *in vitro*, where fertilization occurs in a Petri dish.[6] GIFT is no longer widely practiced.

Intra-Cytoplasmic Sperm Injection

ICSI is currently the most common method of IVF. It consists of injecting a single sperm into an egg with a microscopic needle. If fertilization occurs, the resulting embryo is transferred to a woman's uterus.[7] This treatment is employed where there appears to be poor sperm function or a low sperm count, where a woman's fallopian tubes are blocked or when there is a risk of passing on a genetic disorder.[8]

2.2.2 The Canadian Context

During the 1980s, scientific advances in the area of reproductive technologies and a growing awareness of the legal, ethical and social issues related to reproductive technologies prompted individuals and groups in Canada to pressure the federal government to examine the complex issues related to these technologies. In response to this pressure, the federal government appointed the Royal Commission on New Reproductive Technologies in

---

[3] See *Processing and Distribution of Semen for Assisted Conception Regulations*, S.O.R./96-254. Online at: http://laws.justice.gc.ca/en/F-27/SOR-96-254/text.html (date accessed: February 11, 2004).

[4] Cryopreservation is the process by which embryos are frozen indefinitely in liquid nitrogen. For an explanation of cryopreservation see K. LaGatta, "The Frozen Embryo Debate Heats Up: A Call for Federal Regulation and Legislation" (2002) 4 Fl. Coastal L.J. 99; E. Jackson, *Regulating Reproduction: Law, Technology & Autonomy* (Portland: Hart Publishing, 2001).

[5] "Meeting celebrates IVF Birthday" *Nature* http://www.nature.com/nsu/030721/030721-13.html (date accessed: July 25, 2003).

[6] Jackson, *supra* note 4.

[7] *Ibid.*

October 1989.[9] The mandate of the Royal Commission was quite broad. In addition to the task of examining the current and potential scientific and medical developments related to new reproductive technologies, it was also mandated to consider: (1) the impact of the technologies on society as a whole, (2) their impact on identified groups within society, such as women and children, and (3) the ethical, legal, social, economic and health implications of the new technologies.[10]

After an extensive consultation process with citizens, the scientific and medical communities and the social science community, the Royal Commission released its Final Report in 1993, which included 293 recommendations. Three categories of recommendations were made specifically to the federal government: (1) recommendations regarding the need for criminal legislation to set boundaries around the use of new reproductive technologies, (2) recommendations on establishing and operating a National Reproductive Technology Commission, and (3) recommendations specific to federal departments, such as Health Canada.[11]

The government's final response to the Royal Commission is the recently passed legislation *An Act respecting assisted human reproduction and related research*[12] ("AHR Act"). It is the result of significant consultation with the public, stakeholders and the legal and scientific community. The Act is based on the federal criminal law head of power in s. 91(27) of the *Constitution Act, 1867*.[13] To a large extent, it is patterned after the U.K.'s *Human Fertilisation and Embryology Act 1990* ("HFE Act").[14]

The primary objectives of the proposed legislation are to ensure the health and safety of those using AHR by regulating acceptable practices; to ban certain unacceptable practices based on health and safety, and moral and ethical concerns; and to ensure that AHR research involving the *in vitro* embryo is conducted within a regulated environment.[15]

The Act contains a number of prohibited activities including, but not limited to, human cloning for any purpose; sex selection of an embryo for a reason other than medical; germ-line alteration; creating human/non-human combinations for reproductive purposes; commercial surrogacy and selling or buying human *in vitro* embryos.[16]

The Act also sets out a number of controlled activities, including, but not limited to, the collection, alteration, manipulation or treatment of any human reproductive material for the purpose of creating an embryo; the storage, handling and use of human reproductive material intended to create an *in vitro* embryo; and the licensing of facilities carrying out those controlled activities.[17]

The Act also contains other notable features, such as a privacy scheme that applies to personal health reporting information obtained by a licensed AHR facility and the creation of the AHR Agency of Canada.[18]

The Parliament of Canada passed *An Act respecting assisted human reproduction and related research* on March 11, 2004. The Act received Royal Assent on March 29, 2004.

---

[9] The Royal Commission produced a comprehensive report entitled *Proceed with Care: Final Report of The Royal Commission on New Reproductive Technologies* (Ottawa: Government Services Canada, 1993).

[10] *Ibid.* at 2.

[11] *Ibid.* at 1022.

[12] *An Act respecting assisted human reproduction and related research*, Third Session, Thirty seventh Parliament, 52-53 Elizabeth II, 2004 (passed 12 March 2004 and certain sections proclaimed in force on April 22, 2004). The Act is the reinstated version of Bill C-13, *An Act respecting assisted human reproduction and related research*, 2nd Sess., 37th Parl., 2002 (Second Reading in Senate). The *AHR Act* has a long Parliamentary history as follows: Bill C-13 died on the Order Paper when Parliament was prorogued on November 12, 2003. By a motion adopted on February 10, 2004, the House of Commons reinstated Bill C-13, renumbered as Bill C-6, at the same stage as it had been when the previous session was prorogued. Bill C-13 was originally introduced as Bill C-56, *An Act respecting assisted human reproduction* in the 1st Sess., 37th Parl. (2nd reading 28 May 2002) but died on the Order Paper when Parliament was prorogued on September 16, 2002. A motion was adopted on October 7, 2002, which reinstated Bill C-56, renumbered as Bill C-13, at the same stage as it had been when the previous session was prorogued. Bill C-56 was a recreation of Bill C-47 which died on the Order Paper when an election was called in 1997.

[13] *Constitution Act*, 1867 (U.K.), 30 & 31 Vict., c.3, reprinted in R.S.C. 1985, App. II, No. 5.

[14] *Human Fertilisation and Embryology Act 1990* (U.K.), 1990, c. 37 [hereinafter HFE Act].

[15] Health Canada http://www.hc-sc.gc.ca/english/media/releases/2002/2002_34bk1.htm (date accessed: February 13, 2004).

[16] See *Assisted Human Reproduction Act*, Clauses 5 – 9 for a complete list of prohibited activities.

[17] See *Assisted Human Reproduction Act*, Clauses 10 – 13 for a complete list of controlled activities.

[18] *Assisted Human Reproduction Act*, Clauses 14 – 19 and Clauses 21 – 39.

2.2.3 The Comparative Context

Throughout this chapter, legislation, jurisprudence and policies in relation to AHR from several countries will be examined. Various reasons exist for canvassing the AHR activities in these countries. For example, some countries share our common law tradition, such as the U.K., while other countries share similar constitutional human rights guarantees, such as the United States ("U.S."). The laws of some countries are canvassed to illustrate unique approaches to regulating AHR activities.

Several countries have implemented legislation respecting AHR. For instance, the U.K. has had legislation in place since 1990, which, among other things, established the world's first national regulatory body to oversee AHR activities.[19]

Legislation dealing with bioethics has been in place in France since 1994. In 2002, the French National Assembly undertook to revise this legislation to address activities such as cloning, and embryonic stem cell research.[20]

Three Australian jurisdictions have legislation respecting IVF.[21] In April 2002, the various Australian governmental bodies agreed to develop legislation, which has since been adopted, that would apply across the country to ban certain practices involving the embryo that are deemed unacceptable.[22]

In the U.S., there is no national regulatory scheme for AHR-related activities.[23] Rather, legislation varies among states, with only a few states, such as California, having fairly comprehensive legislation respecting AHR, while most others do not.

2.3 Human Rights Issues Related to AHR

Issues

As mentioned above, three distinct issues will be discussed in this chapter. First, access to AHR services will be discussed. Equality rights, the right to reproductive autonomy, the right to health and the right to benefit from scientific advancement will be explored in relation to access to AHR services. Second, the human rights implications relating to children born following the use of AHR technology will be analyzed from both the perspective of the offspring and the donor of reproductive material. Finally, the human rights issues relating to the dispositional authority over the *in vitro* embryo will be explored. The legal status of the *in vitro* embryo will be examined to determine whether it has any rights. The rights of donors of reproductive material vis-à-vis the *in vitro* embryo and the rights of recipient couples vis-à-vis the *in vitro* embryo will also be analyzed.

2.4 Issue 1: Access to AHR Services

Principles of Non-Discrimination in Relation to Access to AHR Services

In the context of access to AHR, several human rights issues arise, including whether AHR services should be available to everyone, whether they should be publicly funded, and whether the state can limit access to AHR services on the basis of economic considerations, age, marital status, likelihood of success, HIV status, etc. Limitations in relation to access to AHR services on such grounds as age and sexual orientation have been the subject of litigation outside of Canada.

Currently in Canada, AHR services are provided to individuals or couples in either exclusively private clinics or private clinics affiliated with a hospital. In either case, individuals or couples undergoing AHR treatment pay for all of the costs incurred. The only exception is in the province of Ontario, where public funding is provided for certain AHR services on an extremely limited basis.[24]

---

[19] *Supra* note 14.

[20] Three pieces of legislation respecting bioethics have been in place since 1994.
(1) Loi n° 94-654 du 29 juillet 1994: Loi relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prenatal "bioéthique".
(2) Loi n° 94-630 du 25 juillet 1994 : Loi modifiant le livre II bis du code de la santé publique relatif à la protection des personnes qui se prêtent à des recherches biomédicales. Loi dite loi Huriet.
(3) Loi n°94-653 du juillet 1994 : Loi relative au respect du corps humain.
Revisions to these laws are expected to receive final approval in the French Senate in the spring.

[21] The three Australian jurisdictions that have enacted legislation are Victoria, South Australia and West Australia.

[22] Two pieces of legislation have been enacted: (1) *Research Involving Human Embryos Act 2002* and (2) *Prohibition of Human Cloning Act 2002*. Online: http://www.health.gov.au/nhmrc/embryo/ (date accessed: February 13, 2004).

[23] Health Canada, http://www.hc-sc.gc.ca/english/media/releases/2002/2002_34bk7.htm (date accessed: February 13, 2004).

Although no official reports exist detailing instances of discrimination respecting access to AHR services in Canada, there are anecdotal reports of discrimination, particularly on the basis of marital status and sexual orientation.[25]

In the U.S., a blind woman has recently sued a fertility clinic in Colorado alleging discriminatory practices after the clinic refused to continue treating her unless she could demonstrate that she was able to care for a child on her own.[26] Anecdotal reports also exist in the U.S. claiming discrimination on the basis of age, marital status and sexual orientation.

In the U.K., access to AHR procedures is also an issue. Access to National Health Service funded AHR treatment is largely dependant on place of residence, as regional health authorities can set different criteria respecting who is eligible and what services will be funded. Essentially, what has developed is a 'postcode lottery' for treatment.[27] In 1999, the U.K. government announced that it would seek to develop a national strategy for access to AHR to eliminate the postcode lottery system. A draft report was released in August 2003, but guidelines have yet to be formally implemented.[28]

In addition to place of residence, marital status and sexual orientation are potential barriers to accessing AHR services in the U.K. The *HFE Act* states that fertility clinics must take into account "the welfare of any child who may be born as a result of treatment, including the need of that child for a father."[29] Therefore, when considering treatment, clinics must bear in mind that single or lesbian women would be bringing a child into the world without a father. The *HFE Act* provision also requires that the general welfare of any resultant child be considered. Factors such as age, as well as medical conditions, such as HIV or AIDS may play a role in the decision to provide treatment to particular patients.

Discrimination with respect to access to AHR services has been the subject of litigation in both the U.K. and Australia. In the U.K. in *R. v. Sheffield Health Authority, ex parte Seale*,[30] the health authority had set the upper age limit to receive IVF treatment at 35 for publicly funded treatment under the *National Health Services Act*, 1977, due to budgetary constraints and the likelihood of success in patients under 35. Consequently, the claimant, a 37-year-old woman, was denied treatment. The Court held the simple fact that a service was provided did not deny the Sheffield Health Authority the ability to set the circumstances under which the service would be provided, nor did it entitle an individual to demand treatment. The decision to take age into account was held not to be irrational given that success of the treatment decreased with age, and the financial balancing required to provide the service as determined by the legislation.[31]

In *McBain v. State of Victoria*,[32] Dr. McBain challenged the provision in the *Victoria Infertility Treatment Act*, which provided that a woman must either be married or be living with a man in a de facto relationship, on the basis that it discriminated against single women contrary to the *Commonwealth Sex Discrimination Act*. The Court held that there was a conflict and declared that the specific provision of the *Victoria Infertility Treatment Act* was invalid to the extent of the inconsistency.

Also in Australia, a similar decision was reached in *Pearce v. South Australia Health Commission et al.*,[33] where the Court held that the *Reproductive Technology Act* of South

---

[24] Services are only covered in Ontario if both of the patient's fallopian tubes are blocked. However, the services available are not unlimited and other restrictions exist. To date, this policy decision to fund only AHR services for certain individuals has not been challenged on the basis of equality to access AHR services.

[25] *The AHR Act* provides specific mention in clause 2(e) that persons seeking AHR services must not be discriminated against.

[26] CBSNews.com "Blind Woman Suing Fertility Clinic" http://cbsnews.com/stories/2003/11/08/health/main582566.shtml (date accessed: December 5, 2003).

[27] *Supra* note 4 at 197.

[28] K. Horsey, "Access to IVF" BioNews website http://www.bionews.org.uk/update.lasso?storyid=1752 (date accessed November 12, 2003).

[29] *Supra* note 14 at s. 13(5).

[30] (1994) 25 BMLR 1 (Queen's Bench Division).

[31] Note that in this case, publicly funded treatment was at issue.

[32] [2000] FCA 1009 (Federal Court of Australia).

[33] (1996) SASR 486 (Supreme Court of South Australia).

Australia conflicted with the *Commonwealth Sex Discrimination Act.*[34]

A review of the above jurisprudence suggests that if the state is going to provide access to AHR services, it must be done on an equitable basis in accordance with relevant domestic and international human rights law.

The Extent of the States' Obligation in Relation to Access to AHR Services

Another significant issue in relation to access to AHR services is whether the state has a positive obligation to provide access to such services. Three fundamental questions will be examined. First, does a right to reproductive autonomy exist? Second, does a right to health care exist? And finally, does a right to benefit from scientific progress exist?

2.4.1 The Right to Reproductive Autonomy

International Law

There are no specific references to AHR in any international instruments. However, several international instruments set out rights with respect to the family. The *International Covenant on Civil and Political Rights* ("ICCPR")[35] states that "the family is the natural and fundamental unit of society" and sets out the right of men and women of full age to marry and found a family.[36] The *Convention on the Elimination of All Forms of Discrimination Against Women* ("CEDAW")[37] requires States Parties to ensure that women enjoy the right to decide on the number and spacing of their children, as well as the right to access information and education to allow them to meaningfully exercise the right.[38]

The interpretation of these rights, particularly as they relate to AHR, has been varied. For example, some commentators have argued that the text of the provisions relating to family, coupled with the Travaux Préparatoires of both treaties suggest that the rights enunciated were not meant to impose a positive obligation on states to assist in reproduction, but rather were intended to relate to individuals who have a physiological capacity to reproduce.[39] This position is supported by general comment 19, produced by the Human Rights Committee, which states "the right to found a family implies, in principle, the possibility to procreate and live together."[40]

In contrast, others have argued that the obligation of States Parties to ensure individuals enjoy the rights outlined in the above treaties places an obligation upon states to facilitate the right to reproduce, even by artificial means.[41]

Given that the issue of a right of access to reproductive technologies has not been addressed at the international level by any human rights body, it is unclear how the provisions of the ICCPR and the CEDAW would be interpreted in relation to the issue.

France

The French courts have recognized the right to reproductive autonomy. In *Parpalaix c. Centre d'etude et de Conservation du Sperme,*[42] the Court was asked to determine the status of sperm that had been donated by a deceased man. In its discussion of a person's reproductive material, the Court noted that "sperm is the genetic expression of a person's fundamental right to create life or refrain from bearing children."[43]

---

[34] Note that in these Australian cases, public funding was not at issue.

[35] *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171 (entered into force 23 March 1976), [hereinafter ICCPR]. Canada is a party to the ICCPR.

[36] *Ibid.* at Article 23.

[37] *Convention on the Elimination of All Forms of Discrimination Against Women*, 18 December 1979, 1249 U.N.T.S. 13 (entered into force 3 September 1981), [hereinafter CEDAW]. Canada is a party to the CEDAW. This Convention was the product of over thirty years of work by the UN Commission on the Status of Women. The Convention reaffirms the equality rights of women and essentially establishes an international bill of rights for women. Civil rights, the legal status of women and reproductive rights are dealt with in detail. The Convention also outlines an agenda for action by states to guarantee the enjoyment of the rights set out in the Convention. The implementation of the Convention is monitored by the Committee on the Elimination of Discrimination Against Women.

[38] *Ibid.* at Article 16(1)(e).

[39] M.K. Eriksson, *Reproductive Freedom in the Context of International Human Rights and Humanitarian Law* (London: Kluwer Law International, 2000) at 194.

[40] GC No. 19/38 on Article 23 of the ICCPR, UN Doc. CCPR/21/rev.1/Add.2 at para 5.

[41] *Supra* note 39 at 194.

[42] [1984] Trib. Gr. Inst. Creteil, August 1, 1984, Gazette du Palais (G.P.), Sept. 15, 1984.

[43] G.A. Katz, "*Parpalaix c. CECOS: Protecting Intent in Reproductive Technology*" (1998) 11:3 Harvard J. L. & Tech. 683 at 686.

United States

In the U.S., the right to reproductive autonomy (more commonly known as procreational autonomy in the U.S.) is grounded in the privacy and liberty interests of the Fourteenth Amendment to the U.S. Constitution.[44] The U.S. courts have held that the right consists of both the right to reproduce and the right not to reproduce.[45]

In *Skinner v. Oklahoma*,[46] one of the early cases regarding reproductive rights, the U.S. Supreme Court struck down a state law that required sterilization of felons who were convicted of multiple crimes involving moral turpitude. The Court held that "marriage and procreation were fundamental to the very existence and survival of the race" and were to be considered "basic civil rights."[47] The Court thus characterized the right to procreate as a fundamental right.

This position was confirmed in *Eisenstadt v. Baird*,[48] where the Supreme Court held that, "if the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so affecting a person as the decision whether to bear or beget a child."[49]

In *Griswold v. Connecticut*,[50] the right not to procreate was clearly established when the Court upheld the right of married couples to use contraceptives. The Court noted that the fundamental right of privacy included child-bearing decisions and that such decisions ought to be free from unjustified governmental intrusion. The right to use contraception was later extended to non-married individuals in *Carey v. Population Services International*.[51]

Finally, in the landmark decision of *Roe v. Wade*,[52] the U.S. Supreme Court stated that the fundamental right of privacy includes procreation, as well as the decision to terminate a pregnancy.[53] These decisions, at the very least, establish the right to reproduce by natural means without state interference.[54]

The U.S. courts have also discussed reproductive autonomy in cases involving AHR, specifically in the context of disputes over frozen *in vitro* embryos, which will be discussed later in this chapter. In this context, the Tennessee Supreme Court has reaffirmed that, "the right of procreational autonomy is composed of two rights of equal significance – the right to procreate and the right to avoid procreation."[55]

With respect to the right to procreate using technologically assisted means (i.e. AHR), two recent cases from U.S. lower courts provide some insight into whether reproductive rights in the U.S. extend to AHR.

In *Baby M*, [56] a surrogate mother refused to give up the child she was carrying, thereby breaching the contract between her and the intended parents. The Supreme Court of New Jersey held that the contract violated public policy and stated, "the right to procreate very simply is the right to have natural children, whether through sexual intercourse or artificial insemination. It is no more than that."[57]

Two years later, the U.S. District Court for the Northern District of Illinois in *Lifchez v. Hartigan*,[58] held that the Illinois foetal anti-experimentation statute was unconstitutional on grounds of vagueness and impermissible intrusion on a woman's right of privacy. Referring to IVF techniques, the Court stated, "[e]mbryo transfer is a procedure designed to enable an infertile woman to bear her own child. It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."[59]

---

[44] Section 1 of the Fourteenth Amendment of the U.S. Constitution states:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the state wherein they reside. No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

[45] For an excellent summary of the U.S. jurisprudence see: G.J. Annas, "The Impact of Medical Technology on the Pregnant Woman's Right to Privacy" (1987) 13 Am. J. L. and Med. 213.

[46] 316 U.S. 535 (U.S. S.C. 1942).

[47] *Ibid.* at 541.

[48] 405 U.S. 438 (U.S. S.C. 1972).

[49] *Ibid.* at 453.

[50] 381 U.S. 479 (U.S. S.C. 1965).

[51] 431 U.S. 678 (U.S. S.C. 1977).

[52] 410 U.S. 113 (U.S. S.C. 1973).

[53] *Ibid.* at 152 ,153.

[54] E. Price Foley, "Human Cloning and the Right to Reproduce" (2002) 65 Alb. L. Rev. 625; C. Kalebic, "Symposium on Cloning: The Constitutional Question of Cloning Humans: Duplication or Procreation? An Examination of the Constitutional Right to Procreate" (1998) 8 s. Cal. Interdis. L.J. 229.

[55] *Infra* note 193.

[56] *In the Matter of Baby M, A Pseudonym for an Actual Person*, 109 N.J. 396 (Supreme Court of New Jersey 1988).

[57] *Ibid.* at 448.

[58] 735 F. Supp. 1361 (U.S. District Court Northern District of Illinois 1990).

Although the U.S. courts have acknowledged a right to reproduce and the corresponding right not to reproduce, this recognition of the existence of the right to reproductive autonomy has not been translated into a positive obligation on the government to provide AHR services to individuals.

Canada

There are no explicit references to reproductive rights in the *Canadian Charter of Rights and Freedoms* ("*Charter*"), nor does any Canadian jurisprudence exist stating that a right to reproduce is a basic human right. However, the liberty component of s. 7 of the *Charter* has been interpreted by the Supreme Court of Canada ("SCC") to protect a woman's reproductive autonomy. This concept of reproductive autonomy was first recognized in the context of abortion rights.

In 1988, Justice Wilson, writing on her own behalf in *R. v. Morgentaler*,[60] held that the liberty interest in s. 7 included the right to make "fundamental personal decisions without interference by the state."[61] This right included the right to decide whether or not to have an abortion, and as such it was "one that will have profound psychological, economic and social consequences for the pregnant woman."[62] As a result, Wilson J. found that the *Criminal Code* abortion provision at issue was an unjustifiable violation of the right to liberty under s. 7. However, given the impact the provision had on access to and availability of therapeutic abortions, the majority of the Court held that the provision was unconstitutional based on the security of the person component of s. 7.

This interpretation of the liberty interest has subsequently been adopted by the SCC in various contexts including the parental right to make decisions regarding the medical care of children; and the denial of legal aid to a parent in a wardship proceeding.[63]

In *E. (Mrs.) v. Eve*,[64] a mother applied to the court for permission to have her mentally incompetent adult daughter undergo non-therapeutic sterilization. The SCC held that, given the grave intrusion on the individual's rights, parens patriae jurisdiction should never be used to authorize non-therapeutic sterilization. It was also argued before the Court that based on the common law and the fundamental right to reproduce and the corresponding right not to reproduce, which stems from s. 7 of the *Charter*, a U.S.-style substituted judgment test should be adopted. The Court was unwilling to opine as to whether the liberty component of s. 7 protects a fundamental right to reproduce or not reproduce. Rather, the Court concluded that s. 7 was inapplicable in this case because the individual's mother as opposed to the state sought the sterilization. Of significance in this case is the Court's recognition that reproductive decisions are of a serious and deeply personal nature and therefore may qualify as a fundamental personal decision worthy of *Charter* protection.

Reproductive autonomy has also been considered in the child welfare context. In *Winnipeg Child and Family Services v. G. (D.F.)*,[65] the SCC was asked to determine whether a child-welfare agency could place a pregnant woman with a glue-sniffing addiction into the custody of a hospital to protect the developing fœtus. A majority of the SCC rejected the assertion that such action would be justifiable under tort law or *parens patriae* authority. The majority held that a fœtus should not be recognized as a legal person due to the potential interference with the mother's liberty interest. The Court stated that, in the context of tort law, if a duty of care was owed by a mother to her fœtus it could create a situation of conflict between the mother as an autonomous individual and her developing child, with resulting negative consequences for the mother.

---

[59] *Ibid.* at 1376.

[60] [1988] 1 S.C.R. 30.

[61] *Ibid.* at para. 230.

[62] *Ibid.* at para. 241.

[63] *B.(R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315; *New Brunswick (Minister of Health and Community Services v. G.(J.)*, [1999] 3 S.C.R. 46. See also *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307 and *Godbout v. Longueuil (City)*, 1997 3 S.C.R. 844.

[64] [1986] 2 S.C.R. 388.

[65] [1997] 3 S.C.R. 925. For commentary on this case see: M. Randall, "Pregnant Embodiment and Women's Autonomy Rights in Law: An Analysis of the Language and Politics of Winnipeg Child and Family Services v. G. (D.F.)" (1999) 62 Sask. L. Rev. 515; T. Caulfield & E. Nelson, "*Winnipeg Child and Family Services v. G. (D.F.)*: A Commentary on the Law, Reproductive Autonomy and the Allure of Technopolicy" (1998) 36 Alta. L. Rev. (No. 3) 799; F. Baylis, "Dissenting with the Dissent: *Winnipeg Child and Family Services v. G. (D.F.)*" (1998) 36 Alta. L. Rev. (No. 3) 785.

In sum, the Canadian jurisprudence dealing with reproductive autonomy indicates that individuals have a right to be free from interference by the state with respect to fundamental personal decisions. It is highly likely that the decision to reproduce would qualify as a fundamental personal decision of the sort contemplated by the SCC. As a result, the liberty interest contained in s. 7 would likely be engaged if the state attempted to prevent an individual from making a personal decision to reproduce.

Discussion

Elements of a right to reproductive autonomy can be seen in the domestic, international and comparative human rights instruments and their corresponding jurisprudence. In the context of abortion and family planning, reproductive autonomy is quite well developed. The concept of a right to reproductive autonomy has not yet been applied to AHR in Canada or at the international level, and only peripherally in the U.S. in the context of fœtal anti-experimentation laws.

Whether the concept of reproductive autonomy translates into a positive right of access to AHR services remains to be answered. Interference with a fundamental personal decision, such as in *Morgentaler*,[66] where the *Criminal Code* placed restrictions on access to abortion services, is substantially different than calling on the state to take action or provide assistance to enable one to fulfill a personal desire.[67] As one commentator suggested, "a right not to be prevented from having a child would not entail the right to be provided with a child."[68] To date, there is no jurisprudence in Canada to suggest that the state has an obligation to assist individuals in exercising their right to reproductive autonomy. In the U.S., the same is true as the jurisprudence speaks of a right to be free from state interference and the right to submit to medical treatment, as opposed to the right to request state-funded services to exercise the right to reproduce.

2.4.2 The Right to Health

International Law

There are several international human rights instruments that refer to a "right to health". The right to health is clearly not a right to be healthy per se. Rather, the right encompasses a range of health-related benefits, including but not limited to health care, education, child and maternal health, and environmental health.

The first express mention of the right to health is in the *Universal Declaration of Human Rights* ("UDHR"), which provides that "everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services…."[69]

Article 12 of the *International Covenant on Economic, Social and Cultural Rights* ("ICESCR")[70] is considered to be the most authoritative statement on the right to health. It explicitly recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[71] The obligation on States Parties is one of progressive realization in light of available resources. The Covenant sets out the following steps for States Parties "to achieve the full realization of this right":

a. The provision for the reduction of the still-birth rate and of infant mortality and for the healthy development of the child;

b. The improvement of all aspects of environmental and industrial hygiene;

---

[66] *Supra* note 60.

[67] M. Evans, "A Right to Procreate?" in D. Evans (ed.), *Creating the Child* (London: Kluwer Law International, 1996) 127 at 129.

[68] *Ibid.* at 129.

[69] GA Res. 217 (III), UN GAOR, 3rd Sess., Supp. No. 13, UN Doc. A/810 (1948), Article 25(1) [hereinafter UDHR].

[70] *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976) [hereinafter ICESCR]. Canada is a party to the ICESCR.

[71] *Ibid.* at Article 12.

c. The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

d. The creation of conditions which would assure to all medical service and medical attention in the event of sickness.[72]

The UN Committee on Economic, Social and Cultural Rights has examined the scope of the right to health in its general comment on the right.[73] Although the views of the Committee are not binding, they are an indication of how the body responsible for the application of the ICESCR interprets the right to health.

The general comment outlines four elements — availability, accessibility, acceptability and quality — to realize the right to health. Availability relates to the quantity of services, facilities and adequately trained personnel. Accessibility refers to four criteria, including non-discrimination, physical and economic accessibility and access to health-related information. Acceptability encompasses respect for medical ethics, cultural sensitivity and principles of confidentiality. Quality refers to the scientific and medical appropriateness and quality of health services and facilities.[74]

The general comment also imposes three types of obligations upon states. The obligation to respect is largely a negative obligation, which requires states to refrain from action that would interfere with the enjoyment of the right to health. The obligation to protect requires states to take measures to ensure third parties do not interfere with the right to health. The obligation to fulfil requires States Parties to ensure the realization of the right through various means, including legislative, administrative, budgetary and judicial measures.[75]

In relation to women and the right to health, the general comment specifies a need to develop and implement comprehensive national strategies to promote women's health as a means to eliminate discrimination against women.[76] To this end, the comment indicates that national strategies should include measures to prevent and treat diseases affecting women and policies to provide access to health care, including sexual and reproductive services. Reproductive health is also mentioned with respect to the efforts States Parties should undertake to eliminate discrimination against women.[77] Although "sexual and reproductive health" is mentioned in the general comment, in particular in relation to articles 12.2(a) and 12.2(c),[78] no mention is specifically made of AHR. The following definition of reproductive health is provided in the general comment:

> Reproductive health means that women and men have the freedom to decide if and when to reproduce and the right to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice as well as the right of access to appropriate health-care services that will, for example, enable women to go safely through pregnancy and childbirth.[79]

Although the Committee's general comment has made strides to improve States Parties' understanding of the scope and content of the international human right to health, the parameters of the right remain unclear. The U.N. Commission on Human Rights has appointed a Special Rapporteur to further explore and promote the right.[80]

---

[72] *Ibid.* at Article 12.2(a).

[73] Committee on Economic, Social and Cultural Rights, *General Comment No. 14*, UN ESCOR, 2000, UN Doc. E/C.12/2000/4, CESCR [hereinafter General Comment 14].

[74] *Ibid.* at para. 12.

[75] For a summary of the general comment or other literature respecting the international right to health see: S.D. Jamar, "The International Human Right to Health" (1994) 22 S.U.L. Rev. 1; V.A. Leary, "the Right to Health in International Human Rights Law" (1994) 1 Health and Human Rights 25; A.R. Chapman, "Conceptualizing the Right to Health: A Violations Apporach" (1998) 65 Tenn. L. Rev. 389; L. Smith, "Section IV(b): The Right to Health" in K.E. Mahoney & P. Mahoney (eds.), *Human Rights in the Twenty first Century: A Global Challenge* (London: Martinus Nijhoff Publishers, 1993); E.D. Kinney, "The International Human Right to Health: What does this Mean for our Nation and World?" (2001) 34 Ind. L. Rev. 1457; A.R. Chapman, "Core Obligations Related to the Right to Health" in A.R. Chapman & s. Russell (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (New York: Intersentia, 2002).

[76] *Supra* note 73 at para 21.

[77] *Ibid.* at para 21.

[78] *Ibid.* at paras. 14, 16.

[79] *Ibid.* at para 15.

[80] Paul Hunt, a renowned human rights scholar was appointed Special Rapporteur by the U.N. Commission on Human Rights by Resolution 2002/31. In his preliminary report, Paul Hunt identified three primary objectives for his three year mandate: (1) to promote – and encourage others to promote – the right to health as a fundamental human right; (2) to clarify the contours and content of the right to health; and (3) to identify good practices for the operationalization of the right to health at the community, national and international level.

In the *Convention on the Rights of the Child* ("CRC"),[81] the right to health as enunciated in the ICESCR was specifically reiterated in relation to children. In addition, States Parties must take appropriate measures with respect to children's health issues such as lowering infant and child mortality and fighting disease and malnutrition, among other things.[82]

Other international instruments, to which Canada is a party, also refer to non-discrimination in relation to the right to health. In the *International Convention on the Elimination of All Forms of Racial Discrimination* ("CERD"),[83] States Parties undertake to prohibit and eliminate racial discrimination in all forms and to guarantee the right of everyone, without distinction, the enjoyment of the right to public health and medical care.[84] In the CEDAW, States Parties agree to take appropriate measures to eliminate discrimination against women in relation to health care. In particular, states must ensure equal access to health care services, with specific emphasis on pre- and post-natal care.[85] Arguably, these principles of non-discrimination in relation to reproductive services would extend to accessing AHR services.

Several regional conventions, to which Canada is not a party, such as the *European Social Charter*,[86] the *African Charter on Human and Peoples' Rights*[87] *and the Council of Europe's Convention on Human Rights and Biomedicine*,[88] and international bodies, such as the World Health Organization, also recognize a right to health.[89] Further, many States' constitutions include a right to health, including South Africa, the Netherlands, Italy and Hungary.[90]

The international human right to health enunciated in the ICESCR has not been referred to in Canadian jurisprudence respecting access to health care services. Consequently, it is uncertain how a Canadian court would address such a claim and whether such a right would be used to interpret domestic law in a manner that imposes a positive obligation on the state.

Canada

The *Charter* does not contain an explicit 'right to health' or 'right to health care'. However, attempts have been made to use both ss. 7 and 15 of the *Charter* as a basis to claim that the government has a positive obligation to provide or fund particular medical treatments. Given that health care is currently widely accessible in Canada, it is not surprising that a large body of Canadian jurisprudence asserting a right to health does not exist. Nevertheless, it is not difficult to foresee the number of *Charter* claims alleging a right to health increasing as health care costs continue to rise and pressure on federal and provincial budgets continue to escalate.

Application of the Charter in the Health Care Context

The SCC has stated that not all activity in the health care context constitutes governmental action. In *Stoffman v. Vancouver General Hospital*,[91] the Court found internal hospital management issues such as the mandatory retirement policy for doctors were not subject to *Charter* review. Such decisions were not subject to government control pursuant to legislation governing hospitals in the province, and consequently, the hospital was not part of the 'government'.

The issue of *Charter* application was revisited in 1997 *in Eldridge v. British Columbia (Attorney General)*,[92] when the

---

[81] *Convention on the Rights of the Child*, 20 November 1989, 1577 U.N.T.S. 3 (entered into force 2 September 1990) [hereinafter CRC]. Canada is a party to the CRC.

[82] *Ibid.* at Article 24.

[83] *International Convention on the Elimination of All Forms of Racial Discrimination*, 7 March 1966, 660 U.N.T.S. 195 (entered into force 4 January 1969) [hereinafter CERD]. Canada is a party to the CERD. Under this Convention, States Parties pledge, among other things:

- To prohibit racial discrimination by individuals, groups, etc.
- To not engage in any act or practice of racial discrimination against individuals, groups of persons or institutions and to ensure public authorities and institutions refrain from any such acts or practices.
- Not to sponsor, defend or support racial discrimination by persons or organizations.
- To review policies and laws which create or perpetuate racial discrimination.

[84] *Ibid.* at Article 5(e)(iv).

[85] *Supra* note 37 at Articles 11.1(f), 12.

[86] *European Social Charter*, 18 October 1961, 529 U.N.T.S. 89 (entered into force 26 February 1965).

[87] *African Charter on Human and Peoples' Rights*, 27 June 1981, (1982) 21 I.L.M. 58 (entered into force 21 October 1986).

[88] *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, 4 April 1997, E.T.S. No. 164 (entered into force 1 December 1999).

[89] *WHO Constitution*, (1948) 14 U.N.T.S. 186, preamble.

[90] B. Toebes, *The Right to Health as a Human Right in International Law* (Oxford : Intersentia, 1999) at 82, 201, 208.

[91] [1990] 3 S.C.R. 483.

[92] [1997] 3 S.C.R. 624.

SCC was asked to determine whether the *Charter* applied to the actions of a hospital. In particular, the issue in this case was the lack of interpretation services for the deaf in the public health care system. Although the Court previously found that hospitals were private and not government entities, it made a distinction between matters of internal management and delivery of patient care. The provision of medically necessary services by a hospital was found to be a means of delivering a social program under provincial legislation, and thus, fell within the scope of governmental action. Given this conclusion, the *Charter* applied. This decision is particularly significant to *Charter* application in the health care setting because of the Court's willingness to look at the action or activities of the entity in question and whether or not it was fulfilling a governmental objective.[93]

Charter application has not been a significant issue in the existing jurisprudence on the right to health care because claimants have generally challenged legislation allocating resources, which clearly constitutes government action.

Section 7 and the Right to Health

Claimants have attempted to use, most often unsuccessfully, s. 7 to challenge policies relating to the framework of the health care system, such as allocation of billing numbers and private health restrictions.[94] In addition, claimants have suggested that s. 7 includes a right to health care.

In *Fernandes v. Manitoba (Director of Social Services, Winnipeg Central)*,[95] the plaintiff submitted that the denial of funds for him to be cared for at home infringed his s. 7 *Charter* rights because without the care, he would be forced to live in a hospital. The Court held that s. 7 does not protect the plaintiff's desire to live in a certain setting or to have a particular style of living.

In *Ontario Nursing Home Association v. Ontario*,[96] an assertion that an inadequate level of provincial funding to nursing homes violated the right to security of the person was rejected. The Court held that s. 7 did not address property rights or guarantee 'additional benefits' to enhance s. 7 rights.

Similar reasoning was employed in *Brown v. British Columbia*,[97] where the Court held that the provincial government's decision not to fully subsidize the costs of certain drugs used to treat HIV/AIDS did not violate the claimant's s. 7 rights. The Court held that s. 7 does not guard against economic deprivations nor does it provide benefits that would enhance the life, liberty or security of the person.

In *Chaoulli v. Québec (Procureure générale)*,[98] the plaintiffs claimed that the prohibition of parallel private health care insurance violated their s. 7 rights. The trial judge found that s. 7 does not protect pure economic rights. However, rights related to s. 7 rights, that have an incidental economic component, may be protected. With respect to the scope of the rights protected by s. 7, the trial judge stated:

> First, it is clear that the purpose of the *Charter* is not to protect purely economic rights. Second, it must be recognized that there is a body of opinion within the Supreme Court that would extend the scope of s. 7 to guarantee greater autonomy to individuals and, in parallel, would prevent undue interference by the state in people's personal choices. The door is thus not closed to recognition of certain rights intimately tied to and inseparable from the right to life, liberty and security of the person. This will mean some measure of protection for rights known as "ancillary economic rights".[99]

Although the trial judge concluded that there was a deprivation of the applicants' right to life, liberty and security of the person, the deprivation was found to be in accordance with the principles of fundamental justice. The Quebec Court of Appeal dismissed the claimants' appeal.[100] With respect to s. 7, the Court was of the opinion that it was inapplicable on three grounds. First, the right to enter into a contract, which was prohibited by the provisions in question, was an economic right that was not fundamental to the life of a person. Second, to make out a s. 7 violation, the claimants must prove a real or potential and imminent deprivation of the right, which is this case, was not demonstrated. Finally, the Court held that s. 7 could not be used to challenge the correctness of a policy option. This case will be heard by the SCC in the near future.

---

[93] For an excellent discussion of the case law respecting *Charter* application see: M. Jackman, "The Application of the Canadian *Charter* in the Health Care Context" (2000) 9 Health L. Rev. No. 2, 22.

[94] See *Re Mia and Medical Services Commission of British Columbia* (1985) 17 D.L.R. (4th) 385 (B.C.S.C.); *Waldman v. British Columbia (Medical Services Commission)* (1999) 177 D.L.R. (4th) 321. But see *Rombaut v. New Brunswick (Minister of Health and Community Services)* (2001) 240 N.B.R. (2d) 258 (N.B.C.A.).

[95] (1992) 78 Man. R. (2d) 172 (Man. C.A.).

[96] (1990), 72 D.L.R. (4th) 166 (Ont. H.C.J.).

[97] (1990), 66 D.L.R. (4th) 444 (B.C.S.C.).

[98] [2000] J.Q. No. 479 (Sup. Ct.).

[99] *Ibid.* at p. 89 of the English translation prepared by the Translation Service at the Ministère de la Justice du Québec.

[100] [2002] J.Q. No. 759 (Quebec C.A.) leave to appeal to SCC granted [2002] S.C.C.A. No. 280.

As the above jurisprudence illustrates, Canadian courts to date have rejected the notion that the rights enunciated in s. 7 of the *Charter* include a right to a specific type of health care.[101]

Section 15 and the Right to Health

In the context of health care, there are two categories of cases where s. 15 has been raised. The first consists of cases where health care services that are generally available to all are denied to a particular group; while the second category involves cases where there is a refusal to fund a particular treatment required for a specific group of individuals.[102]

The leading Canadian case in the first category is *Eldridge v. British Columbia (Attorney General)*.[103] In this case, the plaintiffs challenged the decision of the province to refuse funding for interpretation services for the deaf as part of the insured medical services available in the province. The SCC found that there was a s. 15(1) violation because the decision not to fund interpretation services effectively deprived deaf residents the opportunity to benefit equally from provincial health care services. Significantly, the Court rejected the province's budgetary justification in the s. 1 analysis. It held that to deny equal access to services that are generally available to everyone did not constitute a minimal impairment of an individual's right to equality pursuant to s. 15(1), particularly when the cost of the service was a very small fraction of the total provincial health care budget.[104]

With respect to the actual substance of health care coverage, the Courts have generally resisted questioning government decisions made with respect to the scope of coverage. For example, the s. 15(1) claim in *Brown v. British Columbia*,[105] where the provincial government refused to completely fund a particular drug used by persons living with HIV/AIDS, was unsuccessful.

Similarly, the challenge by an infertile couple with respect to a provincial decision not to fund particular types of AHR techniques in *Cameron v. Nova Scotia*[106] was also unsuccessful. In this case, the provincial government decided IVF and ICSI treatments were not 'medically required' services and therefore excluded them from the provincial insurance plan. The majority of the Court found that infertility was a disability and that "denial of these procedures, on the ground that they are not medically necessary, created a distinction based on the characteristic of infertility."[107] Further, this distinction perpetuated the view that infertile people are less worthy of value. With respect to the s. 1 analysis, the majority of the Court discussed the role of the government and the distribution of social benefits, stating that:

> In the face of tremendous pressures upon them, they must be "accorded some flexibility" in apportioning social benefits among the vast number of competing procedures and the conditions of patients that call for them. The policy makers require latitude in balancing competing interests in the constrained financial environment. We are simply not equipped to sort out the priorities. We should not second guess them, except in

---

[101] For a summary of the jurisprudence respecting ss. 7 and 15 and health care see: T. Friesen, "The Right to Health Care" (2001) 9 Health L.J. 205; T.A. Caulfield, "Wishful Thinking: Defining 'Medically Necessary' in Canada" (1996) 4 Health L. J. 63; B.F. Windwick, "Health-Care and Section 7 of the *Canadian Charter of Rights and Freedoms*" (1994) 3 Health L. Rev. No. 1 20; A.L. Karr, "Section 7 of the *Charter*: Remedy for Canada's Health Care Crisis? (Part I)" (2000) 58(3) The Advocate 363; Commission on the Future of Health Care in Canada, *How Will the* Charter of Rights and Freedoms *and Evolving Jurisprudence Affect Health Care Costs*, (Discussion Paper) by D. Greschner, 2002.

[102] B. von Tigerstrom, "Human Rights and Health Care Reform: A Canadian Perspective" in *Health Care Reform and the Law in Canada Meeting the Challenge* (Edmonton: The University of Alberta Press, 2002) 157 at 171.

[103] *Supra* note 92.

[104] See also *J.C. v. Forensic Psychiatric Service Commissioner* (1992), 65 B.C.L.R. (2d) 386 (B.C.S.C.) where access to a particular part of the institution was denied to the plaintiff on the basis of gender and budgetary concerns. In this case, the Court found a violation of s. 15(1) and refused to accept justification on the basis of budgetary restrictions. See also C.P. Manfredi & A. Maioni, "Courts and Health Policy: Judicial Policy Making and Publicly Funded Health Care in Canada" (2002) 27(2) Journal of Health Politics, Policy and Law 213.

[105] *Supra* note 97.

[106] (1999), 177 D.L.R. (4th) 611 (N.S.C.A.), leave to appeal to S.C.C. refused [1999] S.C.C.A. No. 531.

[107] *Ibid.* at 654.

> clear cases of failure on their part to properly balance the *Charter* rights of individuals against the overall pressing objective of the scheme under the Act.

To use the words of Sopinka J. ... "it would be unrealistic for this Court to assume that there are unlimited funds to address the needs of all. We must necessarily show considerable deference to the decision makers in this exercise.[108]

Ultimately, the majority found that the violation of s. 15(1) was saved by s. 1. The exclusion of the two procedures was rationally connected to the need to control limited funding and to ensure the safety and efficiency of such treatments. Further, the rights of the claimants were minimally impaired, since other treatments were available. Finally, the effects of the exclusion were outweighed by the benefits of responsible distribution of health care resources.

The opposite result was reached in *Auton (Guardian ad litem of) v. British Columbia (Minister of Health)*.[109] The claimants, minors with autism and their parents, submitted that the denial of early intensive behavioural intervention used to treat autism by the provincial health authority violated both ss. 7 and 15(1) of the *Charter*. The British Columbia Court of Appeal found a s. 15(1) violation. The province's narrow interpretation of medicare legislation resulted in a failure to make appropriate accommodations for the health-care needs of autistic children. This failure to accommodate the already disadvantaged position of these children resulted in differential treatment, based on the enumerated group of mental disability. With respect to s. 1, the Court agreed with the trial judge and held that the violation was not justified. Although, not every refusal to fund treatment for a health care problem can be seen as discrimination, the failure to consider funding treatment for the claimants constituted a statement that the mental disabilities suffered by them are less worthy of treatment. In regards to the allocation of health care resources, the Court stated that it will not always defer to the legislature when compliance with the *Constitution* is at stake, particularly in this case, when the potential expenditure of resources was not extraordinary.[110] This case will be heard by the SCC in the near future.

A fundamental question in these types of cases is the extent to which the government will be able to rely on budgetary constraints in the justification analysis, particularly as the SCC has stated that only in rare cases will costs serve as an appropriate justification under s. 1 of the *Charter*.[111] Also at issue is the government's ability to allocate limited resources to address the health needs of Canadians. In *Cameron*, where the Court found that the violation was minimally impaired given that funding was available for some infertility treatments, there was a clear recognition of the economic realities and their impact on justifying violations of *Charter* rights, whereas in Auton, where no treatment was funded, the Court was clear that economics do not always trump the rights guaranteed in the *Charter*. This is an evolving area of the law and to date, the answer to this issue remains unresolved.

2.4.3 The Right to Benefit from Scientific Progress

The Canadian *Charter* does not contain a reference to a right to benefit from scientific progress. The concept of science-related rights was first articulated in article 27(1) of the UDHR, which served as a model for article 15(1) of the ICESCR. Article 15(1) states:

> The States Parties to the present Covenant recognize the right of everyone:
>
> a. To take part in cultural life;
>
> b. To enjoy the benefits of scientific progress and its applications;
>
> c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[112]

---

[108] *Ibid.* at 667.

[109] [2002] B.C.J. No. 2258 (B.C.C.A.), leave to S.C.C. granted [2002] S.C.C.A. No. 510.

[110] *Ibid.* at paras. 57 – 59.

[111] *Singh v. Canada*, [1985] 1 S.C.R. 177; *Reference re Remuneration of Judges of the Provincial Court of Prince Edward Island*, [1997] 3 S.C.R. 3 at paras. 281–285; *New Brunswick (Minister of Health and Community Services v. G. (J.)*, *supra* note 62 at para 100. For a detailed discussion of s. 1 and health care see: A.L. Karr, "Section 7 of the *Charter*: Remedy for Canada's Health-Care Crisis? (Part II)" (2000) 58(4) The Advocate 531.

[112] *Supra* note 70 Article 15(1).

Article 15(1)(b) of the ICESCR is most relevant to the issue of access to reproductive technologies.[113] At the outset, it should be noted that there is very little literature examining the scope of this right or the obligations on states that flow from this right. Further, there is no reference to this article in Canadian jurisprudence.

One academic has identified the following four core elements of article 15(1)(b) based on an examination of the text of the provision and the corresponding travaux Préparatoires. First, the right to benefit from scientific progress is dependent on the existence of other freedoms, such as free speech, freedom of association and assembly and freedom to access information. Second, the phrase 'to enjoy the benefits' suggests that the right should involve socially beneficial science, as opposed to harmful scientific applications. Third, the enjoyment of the right should be consistent with equality standards enunciated in article 3 of the Covenant. Finally, scientific benefits cannot be enjoyed in states where science has not made progress without the cooperation of the international community.[114]

However, even in the ICESCR the right to benefit from scientific progress is not unlimited. Article 15 contains three related rights that have the potential to conflict. The most notable possible conflict is the tension between the right to benefit from scientific progress and the right to intellectual property rights. It has been suggested that the placement of these rights within the same article reflects the drafter's intention for the rights to be balanced against each other. Some academics have also suggested that to be consistent with a human rights approach the creator's rights should be conditional on contributing to the common good of society.[115]

With respect to access to scientific advancement, one commentator has argued that it is unrealistic to interpret this provision to mean that every person has the right to benefit from every new scientific advancement, particularly in light of the state's budgetary constraints. Further, this author suggests that the general right to benefit from research results does not translate into a specific right to access those specific benefits.[116]

Interestingly, the right to benefit from scientific advancement has not been widely used in the effort to gain access to pharmaceuticals in the fight against HIV/AIDS.[117] Instead, the focus has been on the right to health.

Given the lack of jurisprudence and the general lack of attention to the right to benefit from scientific progress, it is unclear how a Canadian court would respond to an argument that an individual is entitled to access treatment or new technology based on this right. This is particularly so given the inherent balancing that is called for based on a reading of the entirely of article 15 of the ICESCR, coupled with the fact the right to benefit from scientific progress does not expressly exist in Canadian law.

2.4.4 Conclusion

At the present time, there appears to be no concrete obligation on states to fund or provide access to AHR services, either domestically or internationally, in relation to the right to reproductive autonomy, the right to health or the right to benefit from scientific progress. Clearly, refraining from interfering with access to AHR is quite different than actually providing AHR services as a right.

However, if the state regulates AHR activities, the extent to which the state can limit access becomes an issue in which human rights would play a very active role. For example, if the state enacted legislation prohibiting single women, lesbian women or women over a certain age from accessing AHR services, the principles of equality would certainly be engaged. Generally, if a service is regulated, it must be done in an equitable fashion. Although, when public funds are used to provide the service, limits may be acceptable given the particular circumstances.

---

[113] There are also benefit-sharing provisions in the *Convention on Biological Diversity*, 5 June 1992, 31 I.L.M. 818 (entered into force 29 December 1993) and in the *Universal Declaration on the Human Genome and Human Rights, 1997*, G.A. Res. 53/152, 53rd Sess. (1998).

[114] R.P. Claude, "Scientists' Rights and the Human Right to the Benefit of Science" in A.R. Chapman & s. Russell (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (New York: Internsentia, 2002) at 255.

[115] Z. Lazzarini, "Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil" (2003) 6 Yale H.R. & Dev. L. J. 103; Committee on Economic, Social and Cultural Rights, Discussion Paper submitted by A.R. Chapman, "Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c)" UN ESC, 24th Sess., UN Doc. E/C.12/2000/12 (2000).

[116] L. Shanner, "The Right to Procreate: When Rights Claims Have Gone Wrong" (1995) 40 McGill L.J. 823.

[117] But see Z. Lazzarini, *supra* note 115, where she does use Article 15 of the ICESCR to argue a right to access pharmaceuticals. This argument is not generally presented with respect to pharmaceuticals, perhaps because of the reference to intellectual property rights within the same article.

Private and public clinics providing fertility treatments have an obligation to provide their services in accordance with provincial human rights statutes, which prohibit discrimination. Public clinics providing fertility treatments would be required to provide services in accordance with the *Charter*.

2.5 Issue 2: Access to and Disclosure of Information and the Implications for Offspring and Donors of Reproductive Material

Artificial insemination using donor sperm has been practiced by individuals and couples for decades. More recently, the science has developed to allow the use of donated ova and *in vitro* embryos. The discussion will focus mainly on sperm donation, since to date it has been the most prevalent.

The practice of donation of reproductive materials raises significant legal, ethical and moral issues, one of which is the tension between the interests of donors to retain their anonymity and the right of children conceived using donated reproductive materials to know their genetic heritage and the identity of the donor.[118]

2.5.1 The Situation in Canada

Secrecy respecting a donor offspring's conception and genetic origin was often the rule in the past and remains commonplace today. The secrecy around donor offspring is reminiscent of the veil of secrecy that existed around adoption in the past and still does today to a certain extent. Even if donor offspring are told of how they were created, there is often little or no information available about the donor, making it difficult if not impossible for children to learn about their medical history or genetic heritage.

The *Assisted Human Reproduction Act*, described earlier in this chapter, addresses these concerns in a number of ways. Donors will no longer been anonymous to the fertility clinic or the regulatory system. Both the licensee and the regulatory agency created under the Act will be required to retain records containing identifying medical information respecting donors, users and offspring. Prior to accepting a donation of sperm, ova or an *in vitro* embryo, a licensee (clinic or physician) will have to collect and retain the required health reporting information about the donor.[119]

Under the Act, access to the non-identifying medical information regarding the donor will be available to those persons who are considering using a donor's genetic material to create a family or to a person created from the donor's genetic material. However, the identity of the donor will not be disclosed without the donor's written consent.[120] The *Assisted Human Reproduction Act* ensures that parents of children created using donated reproductive material and the children themselves will have access to medical (including genetic) information, while simultaneously respecting the wishes of the donor not to disclose his or her identity.

2.5.2 The Situation in Other Countries

In the mid 1980s, Sweden became the first country to grant mature donor offspring the right to obtain identifying information about their sperm donor.[121] The information that must be provided to the 'mature child' includes the identity of the donor, as well as information relating to the donor, such as physical features. Austria also allows donor offspring to obtain information about sperm donors.[122]

The Australian state of Victoria enacted legislation in 1995 that grants children born as a result of gamete donation and their offspring the right to access both identifying and non-identifying information.[123] The legislation also provides donors and recipients of donated gametes and *in vitro* embryos the right to access non-identifying information about each other. The donors or recipients may only access identifying information in relation to the donors and recipients respectively, with the consent of the other party.

---

[118] We would like to acknowledge Elaine Menard, Counsel, Human Rights Law Section for her valuable assistance and comments on this portion of the chapter.

[119] *Assisted Human Reproduction Act*, clause 14. Health reporting information is defined in clause 3 of the Act as "the identity, personal characteristics, genetic information and medical history of donors of human reproductive material and *in vitro* embryos, persons who have undergone assisted reproduction procedures and persons who were conceived by means of those procedure."

[120] *Assisted Human Reproduction Act*, clauses 15, 18.

[121] C. Gottlieb et al., "Disclosure of donor insemination to the child: the impact of Swedish legislation on couples' attitudes" (2000) 15(9) Human Reproduction 2052.

[122] Note that Swedish and Austrian laws only apply to sperm donors.

A dual system exists in Iceland where donors can choose to donate anonymously or non-anonymously.[124] While in some countries, such as France, Norway and Denmark, children born as a result of donation are not allowed access to any information about their biological parents.[125]

No legislation exists in the U.S. respecting the release of donor information to the resultant offspring. Rather, professional associations, such as the American Society for Reproductive Medicine, have produced recommendations and guidelines addressing the release of donor information.[126] Some sperm banks in the U.S. do offer non-anonymous donor insemination programs, whereby identifying information may be released to a donor offspring upon request at age 18.[127]

In the U.K., the regulatory body created pursuant to the HFE Act collects basic information from donors. This information includes the name, place of birth, date of birth, height, weight, ethnic group, eye colour, skin colour, and hair colour. Information is also collected about the donor's occupation, religion and interests, although the amount of information collected under these categories is left to the discretion of the donor. Under the current U.K. legislative scheme, the donor offspring cannot be given information that would identify the donor. However, individuals are entitled to find out at age 16 whether they may be related to someone they intend to marry. At age 18 individuals are entitled to find out whether their birth was a result of treatment using donated reproductive material.[128]

In 2002, the U.K. government undertook a consultation process on this issue, which was followed by a statement from the government indicating that 'new plans' would be formulated to allow donor offspring to find out more information about their donor once further research is completed.[129] Recently, the U.K. government announced that a change in the law is planned which would allow children born as a result of sperm, eggs or embryos donated after April 2005 to access the identity of their donor when they reach the age of 18. The earliest 18 year olds will be able to access this information is in 2023.[130]

2.5.3 Arguments For and Against the Disclosure of Donor Information

Advocates and opponents of donor anonymity agree that non-identifying medical and genetic information should be disclosed to offspring. However, the release of identifying information remains a controversial issue.

Proponents of a non-anonymous donation scheme cite the emotional void felt by donor offspring caused by not knowing the donor's identity. Further, knowing the identity of the donor contributes to the development of the donor offspring's sense of identity and connection to their biological history.[131] Proponents also note that knowing the identity of the donor could assist in preventing incestuous relationships. This is particularly significant because, in the absence of guidelines or regulations, a donor could be a biological parent to numerous children within a given geographical area who do not realize they are half-siblings.[132]

---

[123] *Infertility Treatment Act 1995.*

[124] L. Firth, "Gamete donation and anonymity: The ethical and legal debate" (2001) 16(5) Human Reproduction 818.

[125] *Ibid.*

[126] See American Society for Reproductive Medicine, 2002 Guidelines for Gamete and Embryo Donation, http://www.asrm.org/Media/Practice/practice.html#Guidelines (date accessed: November 26, 2003).

[127] For example: The Sperm Bank of California has been open since 1982 and children conceived using sperm from this bank who have since reached the age of 18, have contacted their biological fathers.

[128] HFE Act, *supra* note 14. See the relevant background paper prepared by the HFEA online at: http://www.hfea.gov.uk/PressOffice/Backgroundpapers/Eggdonation.

[129] Donor Information Consultation: Providing information about gamete or embryo donors, DoH, 2002; Government Press Release on donor-conceived children, issued January 2003, http://www.pm.gov.uk.

[130] "British sperm, egg donors to lose anonymity" *CBC News* (21 January 2004), online: http://www.cbc.ca/stories/2004/01/21/sperm_donors040121 (date accessed: February 13, 2004).

[131] M.L. Shanley, "Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs" (2002) 36 Law & Soc'y Rev. 257; J. Johnston, "Mum's the Word: Donor Anonymity in Assisted Reproduction" (2002) 11 Health L. Rev. No. 1 151.

[132] K.E. Koehler, "Artificial insemination: In the Child's Best Interest?" (1996) 5 Alb. L. J. Sci. & Tech. 321.

One of the most often cited reasons to retain some level of anonymity in gamete donation is to encourage donation. Donors are reluctant to have their identities disclosed because they are fearful of being found legally responsible for any resultant child. It has been suggested that a non-anonymous donation system would result in a significant shortage or even a complete lack of donors.[133] However, this has not been the case in Sweden. After a non-anonymous system was introduced in Sweden, the number of donors initially went down, but thereafter returned to normal rates of donation.

The Royal Commission on New Reproductive Technologies identified a decrease in the number of donors as a problem in its report and recommended that legislation be adopted in the provinces to ensure that a donor's rights and responsibilities of parenthood are severed by the act of sperm donation.[134]

To date, only Quebec, Newfoundland and the Yukon have taken legislative action to clarify the legal status of sperm donors such that they cannot be found in law to be a parent. For example, Quebec's *Civil Code* clearly provides that there is not a bond of filiation between the contributor of genetic material and the resulting child. However, in Newfoundland and the Yukon, an ovum or *in vitro* embryo donor could be found to be a parent in law. In the remaining provinces and territories, it is possible that a sperm, ovum or *in vitro* embryo donor could be found in law to be the parent of a child created with his or her reproductive material, with a legal obligation to provide support. Alberta is in the process of updating and consolidating various provincial statutes dealing with family law matters. Parentage in the context of surrogacy and artificial insemination is included in the new legislation, which has yet to come into force.

Those in favour of retaining an anonymous system also argue that anonymity protects the recipient family from unwanted emotional or legal intrusions by the gamete or *in vitro* embryo donor.[135] In addition, secrecy also protects and preserves the bond between the offspring and the parent that is not biologically related to the child.[136]

2.5.4 Children Born as a Result of Donated Reproductive Material and the Right to Know One's Genetic Heritage

International Law

Articles 7(1) and 8 of the *Convention on the Rights of the Child* ("CRC") have been referred to as the authority for a child's right to know his or her genetic heritage at international law.[137]

> Article 7 states:
>
> 1. The child shall be registered immediately after birth and shall have the right from birth to a name, the right to acquire a nationality and, as far as possible, the right to know and be cared for by his or her parents.
>
> 2. States Parties shall ensure the implementation of these rights in accordance with their national law and their obligations under the relevant international instruments in this field, in particular where the child would otherwise be stateless.
>
> Article 8 states:
>
> 1. States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognized by law without unlawful interference.
>
> 2. Where a child is illegally deprived of some or all of the elements of his or her identity, States Parties shall provide appropriate assistance and protection, with a view to re-establish speedily his or her identity.

Although both articles 7 and 8 can be interpreted to support a variety of arguments or positions respecting the rights of children, it is important to understand the origin of the provisions so as to inform their interpretation. The primary goal of article 7 was to address the problem of children's statelessness by immediately requiring a child to be linked to his or her parents.[138] Article 8 was developed as a means of reuniting separated families, and was particularly devised to address military actions in Argentina where newborn babies were taken from their parents at birth and given to couples that supported the military regime.[139]

---

[133] Johnston, *supra* note 131.
[134] *Supra* note 9 at 467.
[135] *Supra* note 120.
[136] Johnston, *supra* note 131.
[137] *Supra* note 39 at 199.

Article 7 of the CRC

The word 'parent' is not defined in the article or anywhere else in the CRC. The lack of clarity resulting from the absence of a definition has led some countries to enter reservations or declarations to try to set out the parameters of their understanding of the word, particularly as it relates to adoption or TI.[140]

There are two potential interpretations of the term 'parent' in article 7(1) as it relates to donors of reproductive material. On the one hand, the term 'parent' could refer to the person(s) who made the decision to have and raise the child using donated reproductive material as opposed to the person who donated the reproductive material. On the other hand, the term 'parent' could include one's genetic parents, one's birth parents and one's psychological parents (individuals who may have cared for the child for a significant period of time). The latter has been accepted as a reasonable interpretation of this article of the CRC by the authors of the UNICEF Implementation Handbook.[141]

It is important to note the inclusion of the qualification 'as far as possible' and the exclusion of any reference to the 'best interests of the child' in article 7(1). An examination of the travaux Préparatoires reveals that in an earlier version of the article, the phrase 'as far as possible' did not appear. It was included after concerns were raised that an unrestricted right to know one's parent could not be applied in all circumstances. For instance, certain states noted that their domestic legislation permitted 'secret adoptions' where adopted children did not have the right to know the biological parent's identity.[142]

With respect to the lack of a reference to the 'best interests of the child', during the drafting of the article a proposal was put forward to include the phrase, however, it was rejected. The authors of the UNICEF Implementation Handbook suggest that the phrase 'as far as possible' contained in article 7(1) is stricter and less subjective than the phrase 'best interests of the child' and implies that if possible, children are entitled to know their parents, even if it is not in their best interests.[143] However, the authors do acknowledge that given the nature of the CRC as a whole, particularly the recognition in article 3 that the best interests of the child shall be a primary consideration,[144] a child could be prevented from knowing his or her parent if it would cause definite harm in an extreme circumstance. The authors also note that in relation to a child's knowledge of their origin, what is in the best interest of the child may change over time, particularly as the child grows older.[145]

The authors of UNICEF's Implementation Handbook have identified three situations where the right to know one's parent may not be able to be realized. First, where it is not possible to identify the parent; second, where the mother refuses to identify the father; and finally, where the state determines that the parent's identity should not be revealed (e.g. secret adoption & TI).[146] The authors note that this final situation appears to limit the child's right to know his or her genetic parents unnecessarily and points to countries such as Sweden and Austria to illustrate that non-anonymous systems do work.[147] Further, the phrase 'as far as possible' implies that if the possibility exists for donor identification, the child should be allowed to know his or her biological parents.

---

[138] J. Fortin, *Children's Rights and the Developing Law*, (London: Butterworths, 1998) at 314.

[139] *Ibid.*

[140] For example, Czech Republic, CRC/C/2/Rev.8, p. 28 and Poland CRC/C/2/Rev.8, p. 35.

[141] R. Hodgkin & P. Newell, *Implementation Handbook for the Convention on the Rights of the Child*, (New York: United Nations Children's Fund, 2002) at 117.

[142] For example, the U.S., the former German Democratic Republic and the former U.S.S.R.

[143] *Supra* note 141 at 117.

[144] Article 3(1) of the CRC states that:

> 1. In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

Note that the provision states the best interests of the child shall be *a* primary consideration as opposed to *the* primary consideration. The *travaux préparatoires* indicates that an earlier draft stated the best interests of the child shall be *the* paramount consideration. However, concerns were expressed with this wording, particularly given that other parties might have equal or even superior legal interests in some cases and that in some situations, competing interests, such as the interests of justice and society at large, may have equal or greater importance compared to the interests of the child.

[145] *Supra* note 141 at 118.

[146] *Ibid.* at 119.

[147] *Ibid.* at 118.

The Committee on the Rights of the Child has expressed concern in the past regarding the potential conflict that exists between article 7(1) and state policies that allow sperm donors to remain anonymous.[148] Although persuasive, there is considerable debate with respect to how much emphasis should be placed on the Committee's views.

Article 8 of the CRC

Article 8 of the CRC, includes the following three components as part of a child's identity: nationality, name and family relations. The references to nationality and name are generally well-understood concepts, while the phrase "family relations as recognized by law" is not defined in the CRC and does not appear to have a precise meaning. Whether article 8 provides a foundation to argue that a donor offspring has the right to know his or her genetic parent turns on the meaning of 'family relations'.

'Family relations' has several possible interpretations, particularly given that 'family' is defined differently in different cultures. It could be argued that 'family relations' should be interpreted narrowly, given the facts that gave rise to the development of article 8. As mentioned above, the provision was drafted in response to the situation where newborn children were forcefully separated from their parents. In the context of donor offspring, the genetic parent willingly donates reproductive material knowing that he or she will likely never know the resultant offspring. The donor is not forced or coerced to donate.[149]

Conversely, the authors of the Implementing Handbook have interpreted the phrase 'family relations' as recognizing that the identity of a child encompasses more than child's immediate family.[150] In addition, the authors note that children have a capacity to embrace a number of relationships, which is often not acknowledged. Consequently, knowing the identity of the biological parent is not necessarily in conflict with the best interests of the donor offspring or adopted child.

An examination of the Travaux Préparatoires reveals that in the drafting stage, a representative from Mexico urged that more exacting language should be used in article 8(1) to define the States Parties' commitments. In particular, the representative suggested that the biological elements of the identity should be included in the provision.[151] However, this suggestion was not incorporated into the provision.

In sum, there appears to be little consistency with respect to the manner in which the obligations under the CRC have been interpreted. Some State Parties to the CRC have not changed their legislation regarding anonymous donations, whereas others have done so citing the CRC as the impetus. For example, in its efforts to ensure that the obligations set out in the CRC are fulfilled, Austria amended its donor legislation such that donations of sperm may no longer be anonymous.[152]

In Australia, the South Australia Council on Reproductive Technology has recently prepared a discussion paper regarding access to identifying information regarding donors of reproductive materials. In it, the authors found that legislative and regulatory instruments that blocked access to identifying information pertaining to donors appeared to contravene article 8 of the CRC, in particular the phrase "some or all of the elements of his or her identity."[153] The authors of the paper suggested that, given this phrase, the biological aspects of one's identity should not be withheld from a child conceived using donated reproductive material.

---

[148] *Ibid.* at 119.

[149] The fact that donors are not forced or coerced to donate is likely true for sperm donors. However, it is less obviously so with egg donors. There are some concerns surrounding the subtle coercion of egg 'donors' who have no way to access IVF services but to 'donate' their eggs. Two arrangements are currently in use. *Egg giving* is an arrangement where a woman seeking IVF goes through one cycle in which her eggs are retrieved and then donated. The woman then goes on to have another cycle for her own benefit at a reduced cost. *Egg sharing* is an arrangement where a woman seeking IVF undergoes one cycle in which her eggs are retrieved. Some of these eggs are used for her benefit, and some are donated to another woman. The woman donating her eggs receives a reduction in the cost of IVF. On December 1, 2003, the HFEA issued a statement to the effect that egg giving should no longer be practiced. See online at: http://www.hfea.gov.uk/PressOffice/Archive/1070272120 (date accessed: February 11, 2004).

[150] *Ibid.* at 125.

[151] S. Detrick, ed., *The United Nations Convention on the Rights of the Child: A Guide to the "Travaux Preparatoires"* (London: Martinus Nijhoff Publishers, 1992).

[152] *Supra* note 39 at 200.

[153] South Australia, "Conception by Donation: Access to identifying information in the use of donated sperm, eggs and embryos in reproductive technology in South Australia" Discussion Paper by the South Australian Council on Reproductive Technology, April 2000.

It is difficult to determine exactly how much latitude these provisions give a State Party to restrict access to the identity of one's biological parents. Clearly, if a right does exist, it is not absolute. There are some circumstances, such as when a parent is dead, where it is not possible for a child to know his or her parent. Moreover, there appears to be no consensus amongst States Parties in interpreting the relevant rights contained in the CRC with respect to children born using donated reproductive materials.

With respect to the CRC's effect in Canada, the SCC and the Quebec Court of Appeal have stated that international human rights law, including the CRC, whether incorporated into domestic law or not, may serve as a tool for interpreting domestic legislation, as well as for the judicial review of administrative action.[154]

European Convention for the Protection of Human Rights and Fundamental Freedoms

The European Court has considered article 8 of the *European Convention for the Protection of Human Rights and Fundamental Freedoms* ("the Convention"), which contains the right to private and family life, in relation to access to personal information.[155] Significantly, the Court has not defined an individual's right to 'respect for private life' narrowly. Rather, it has stated that it encompasses physical and psychological integrity and may extend to physical and social identity. Moreover, to a certain extent, it may also include the right to establish and develop relationships with other individuals.[156]

In *Gaskin v. U.K.*,[157] the claimant attempted to gain access to his childhood records kept during the time he was in foster care. The Court found that the information contained in the records was highly personal and was likely his primary source of information about his past. Therefore, article 8 of the Convention was engaged. The Court found that 'respect for private life' requires that individuals should be able to access information relating to their identity and that the state should not bar an individual from such information without particular justification. As a result, the Court concluded that right to private and family life had been breached.

However, not every case alleging a breach of private and family life has been successful before the Court. In *Martin v. U.K.*,[158] the claimant attempted to access personal records held by authorities. Although the Court found that article 8 was engaged, it concluded that no positive obligation existed to disclose the information, largely because the disclosure position taken by the authorities was balanced.

Germany

In 1989, the German Constitutional Court concluded that based on the constitutional right to privacy, a child has a right to know the identity of his or her parents.[159] This right to privacy is not absolute and can be limited through regulations, as long as the regulations are proportionate and are not enacted for an unconstitutional purpose. On the basis of this limited definition of the right to privacy, the anonymous donation of reproductive materials is prohibited.[160]

U.K.

In the U.K., a test case was recently brought to obtain non-identifying information and identifying information (a limited amount of information was sought only by one claimant) concerning sperm donors.[161] Both claimants, an adult born before the *HFE Act* was enacted, and a child born after the *HFE Act* was passed into law, were conceived using donor insemination. The plaintiffs claimed that article 8 and, to a limited extent, article 14 of the *European Convention for the Protection of Human Rights and Fundamental Freedoms*[162] applied.

---

[154] *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817; *Reference Re: Bill C-7 respecting the criminal justice system for young persons*, [2003] Q.J. No. 2850. (Quebec C.A.)

[155] Article 8 of the Convention states:

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

[156] *Niemietz v. Germany*, (1992) 16 EHRR 97 at para. 29.

[157] 1989) 12 EHRR 36.

[158] (1996) 84 D & R 169.

[159] E. Deutsch, "Assisted Procreation in German Law" in D. Evans (ed.), *Creating the Child* (London: Kluwer Law International, 1996) at 337; *supra* note 39 at 200.

[160] Deutsch, *ibid.* at 338.

[161] *R (on the application of Rose and another) v. Secretary of State for Health and another*, [2002] 3 FCR 731 (Q.B. Administrative Court).

Whether these rights were engaged was the subject matter of the hearing. After reviewing the various domestic and European decisions relating to article 8, which protects an individual's right to respect for his private and family life and his home, the Court outlined the following general principles:

- Respect for private and family life requires that everyone should be able to establish details of their identity as individual human beings. This includes their origins and the opportunity to understand them. It also embraces their physical and social identity and psychological integrity.
- Respect for private and family life comprises to a certain degree the right to establish and develop relationships with other human beings.
- The fact that there is no existing relationship beyond an unidentified biological connection does not prevent article 8 from biting.[163]

Accordingly, the Court concluded that article 8 was engaged in respect of both identifying and non-identifying information. However, the Court noted that whether article 8 had been breached was an entirely different matter that was not at issue in the case. Following the Court's ruling, the case was suspended pending the outcome of the U.K. government's consultation process regarding the release of donor information to offspring.

Canada

In Canada, legislation and government action must comply with the *Charter*. To the extent that AHR activities do not come within either legislation or government action, the *Charter* may or may not apply.[164] The *Charter* would apply if legislation or regulations interfered with an offspring's ability to learn the identity of his or her biological parent. The *Assisted Human Reproduction Act* allows an offspring to access the identity of the donor, but only with the donor's written consent.

With the passing of the Act, a primary human rights issue is whether the offspring's right to security of the person under s. 7 of the *Charter* is infringed because he or she would not be able to know the identity of the donor without the donor's consent.

There is no jurisprudence in Canada respecting the *Charter* rights of either the offspring or the donor. However, there is a limited amount of jurisprudence respecting adoption. Although similarities and differences have been identified between adopted children and donor offspring, this jurisprudence provides a useful starting point to analyze whether there is a right to know one's biological parent.[165]

The first stage of the s. 7 analysis is to determine whether there has been a deprivation of life, liberty or security of the person, which requires an examination of the impact upon an individual of not knowing the identity of one's biological parent. If so, it must be determined whether that deprivation is in accordance with the principles of fundamental justice.

In *R. v. D.D.W.*,[166] an individual accused of incest argued that the provisions relating to confidentiality in the provincial Adoption Act infringed his security of the person. The accused attempted to gain access to the adoption records of the complainant to prove that he was not the biological father. The Court held that the accused's security of the person was engaged, but that the provisions in the legislation relating to disclosure were in accordance with the principles of fundamental justice.

---

[162] As adopted in Sch 1 of the U.K. *Human Rights Act, 1998*. Article 8 is reproduced above. Article 14 states:

> The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.

[163] *Supra* note 161 at para 45.

[164] But see the *Processing and Distribution of Semen for Assisted Conception Regulations*, *supra* note 3, enacted pursuant to the *Food and Drugs Act*. These regulations govern the collection and distribution of semen.

[165] In its report, the Royal Commission on New Reproductive Technologies outlined some of the differences between adopted children and children conceived through the donation of reproductive materials at as follows:

> When a couple raises an adopted child, neither is biologically related to that child; when a couple raises a DI child, only one of them is the biological parent. In adoption, the child already exists and is placed for adoption because the mother is unable to raise the child; in DI situations, the child is conceived deliberately with the intent of nurturing and raising it. Adoption deals with finding a family for an existing child, while DI deals with the deliberate formation of a family by having a child.

[166] [1994] B.C.J. No. 3284 (B.C.S.C.).

In *Ferguson v. Director of Child Welfare et al.*,[167] an adult adoptee sought to learn the identity of her birth mother. The Court held that unless exceptional circumstances existed, beyond the adoptee's natural curiosity, the confidentiality provisions in the legislation must be respected. The Ontario Court of Appeal agreed and also held that s. 7 of the *Charter* had no bearing on the particular provision of the legislation in question.

In contrast, an 18-year-old adoptee was granted access to her adoption file in *Ross v. Prince Edward Island (Supreme Court, Family Division, Registrar)*.[168] At the time of her adoption, the legislation in force did not address the issue of disclosure. The Court found that the adoptee "should have the right to know her heritage" and "neither her natural parents nor her adoptive parents should have the right to keep her uninformed of her background."[169] However, no reference was made to the *Charter* in this decision.

In the very limited (and dated) jurisprudence respecting adoption records, the security of the person component of s. 7 has not been interpreted to include a right to know one's genetic heritage. However, since these cases, the Court has elaborated upon the scope of the right to security of the person, particularly as it relates to one's psychological integrity.

In the criminal context, it is well established that one's security of the person includes one's psychological integrity.[170] In addition, the SCC has recently had the occasion to comment on the scope of the right to security of the person with respect to parents in child protection actions. In *New Brunswick (Minister of Health and Community Services) v. G. (J.)* ("G.(J.)"),[171] the Supreme Court recognized that the right to security of the person protects both physical and psychological integrity and that s. 7 is not limited to purely criminal matters. The Court was careful to make clear that not all state interferences with the parent-child relationship will constitute an infringement of the parent's security of the person. Rather, the state action must have "a serious and profound effect on a person's psychological integrity" and must be more than "ordinary stress or anxiety," which was the case in this instance.[172] One year later the Court applied the reasoning developed in *G.(J).* in *Winnipeg Child and Family Services v. K.L.W.* ("K.L.W."),[173] and concluded that the apprehension of a child placed more than ordinary stress and anxiety on a mother, and consequently the mother's security of the person was engaged. The Court also recognized in *G.(J.)* and *K.L.W.* that given the link between a child's life and parent's life, the child's security of the person may also be engaged if the two are separated.[174]

These above-mentioned child protection cases must be contrasted with other circumstances where the state has interfered with the parent-child relationship yet the parent's security of the person was not engaged, such as when a child was incarcerated or conscripted into the military.[175] This was the case in *Augustus v. Gosset*,[176] where the SCC found that the negligent killing of a child by the state (a police officer) did not engage the parent's s. 7 *Charter* rights. In *G.(J.)*, Lamer C.J. (as he was then) reconciled these conflicting outcomes by distinguishing the impact or 'injury' on the parent. He noted that in child custody proceedings, such as *G. (J.)* or *K.L.W.*, a parent is publicly labelled as unfit or incapable of caring for one's child, which engages that parent's security of the person. Whereas, in the other examples, the killing of one's child by the state or incarceration, the interference by the state with the parent's psychological integrity is not vis-à-vis their role as parents and is not interfering in the intimacies of the parent-child relationship.[177]

This jurisprudence helps to give meaning to a parent's right to security of the person. But in the case of a donor offspring's right to know his or her parents, it is the child's security of the person that is at issue. Are the above scenarios where the Court has found an infringement of a parent's security of the person applicable to a child's security of the person? With respect to the first scenario of the state making a public declaration of parental fitness, it is difficult to imagine a situation where the state would make a public declaration condemning a child's fitness or role in the parent-child relationship. The second scenario, where the state interferes with the intimacies of the parent-child relationship, is equally inapplicable because in the case of the offspring there is no existing relationship within which the state could interfere.

---

[167] (1983), 40 O.R. (2d) 294 (Ont. County Court).

[168] [1985] P.E.I.J. No. 1 (P.E.I. Supreme Court).

[169] *Ibid.* at para. 24.

[170] *R. v. Morgentaler*, *supra* note 60; *Rodriguez v. R.*, [1993] 3 S.C.R. 519.

[171] *Supra* note 63.

[172] *Ibid.* at para. 60.

[173] [2000] 2 S.C.R. 519.

[174] *Supra* note 63 at para. 76; *ibid.* at para. 12.

[175] *Supra* note 63 at para. 63; R.J. Sharpe, K.E. Swinton & K. Roach, *The Charter of Rights and Freedoms*, 2nd ed. (Toronto: Irwin Law Inc. 2002) at 184.

[176] [1996] 3 S.C.R. 268.

[177] *Ibid.* at para. 64.

The Court's unwillingness to define security of the person broadly should also be noted. In *G.(J.)*, Lamer C.J. (as he was then) stated that a broad definition of security of the person would open the government to increased challenges and would lead to the trivialization of a constitutionally protected right. Further, in *Blencoe*, the Court concluded that the type of stress and anxiety suffered by the claimant after a state-caused delay in a human rights proceeding was not the type that should be elevated to "the stature of a constitutionally protected s. 7 right."[178]

While the *AHR Act* allows the disclosure of the donor's identity, with his or her written consent, this may affect the psychological integrity of some offspring. On the other hand, it may cause no stress or anxiety to others.

If a court did find that a child's security of the person was infringed, it would look to the balancing of interests of other parties involved, such as the donor and recipient family, in the analysis of the principles of fundamental justice.

Finally, it must be noted that a broader issue is whether or not s. 7 of the *Charter* extends to infringements that occur outside the sphere of the justice system and its administration. Most recently this issue has been addressed in *Gosselin v. Quebec (A.G.)*.[179] One issue in *Gosselin* was whether the Quebec social assistance scheme in place during the 1980s infringed the s. 7 rights of a class of individuals under the age of 30. The majority found that the implication of the administration of justice, the usual requirement for the engagement of s. 7, was lacking. Although the Chief Justice, for the majority, referred to the statement by former Chief Justice Dickson in *Irwin Toy Ltd. v. Quebec* (A.G.)[180] that s. 7 might protect economic rights fundamental to human survival, her analysis focused on positive versus negative rights. Consequently, the question of whether or not a s. 7 claim must be connected to the administration of justice was left open. Clearly, a definitive answer on this question has yet to come out of the SCC. As a result, whether or not s. 7 rights are engaged at all with respect to the security of the person of a donor offspring would necessarily have to be addressed.

2.5.5 Donors of Human Reproductive Material and the Right to Privacy

International Law

Both the UDHR and the ICCPR contain similar provisions protecting against arbitrary interference with one's privacy, family, home or correspondence.[181] Although not generally referred to specifically in Canadian jurisprudence, these provisions may serve as a useful tool to inform and assist in the interpretation of the privacy rights contained in ss. 7 and 8 of the *Charter*.

U.S.

In California, the issue of a sperm donor's right to privacy was recently challenged. In *Johnson v. The Superior Court of Los Angeles County, et al.*,[182] a six-year-old child who had been conceived by donor insemination was diagnosed with a genetically transmitted kidney disease, linked to the anonymous sperm donor. The evidence revealed that the sperm bank knew of the donor's family history of kidney disease, yet continued to use the donor's sperm. The Johnsons sued the sperm bank for breach of contract, fraud and negligence. During discoveries, the recipient family attempted to obtain information from the sperm bank that would have revealed the identity and medical history of the sperm donor in question. The sperm bank refused because such disclosure would have infringed the donor's right to privacy. Using a private investigator, the Johnsons located the individual they believed to be the donor and attempted to compel a deposition and production of documents, which was the particular issue addressed by the Court.

---

[178] *Blencoe*, *supra* note 63 at para. 97.

[179] [2002] SCC 84.

[180] [1989] 1 S.C.R. 927.

[181] Article 12 of the UDHR states:

> No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Article 17 of the ICCPR states:

1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.
2. Everyone has the right to the protection of the law against such interference or attacks.

[182] 80 Cal. App. 4th 1050 (Court of Appeal of California 2000).

The Court recognized that the sperm donor in question and his family have a constitutional right of privacy, both under the California Constitution and the federal Constitution. Further, the Court acknowledged that an individual's medical history, along with the disclosure of one's identity falls within the established realm of privacy. However, the Court found that the donor's reasonable expectation of privacy was lessened because he donated over 320 samples to the sperm bank. The Court concluded that it was unreasonable for the donor to expect that his medical history and even his identity would not be revealed, given the significant number of donations.

While acknowledging that a right of privacy exists, the Court also noted that the right is not absolute. It must be balanced against other compelling state interests. In this case, the Court found a number of compelling state interests, including protecting the health and safety of children conceived using donated reproductive material. The Court concluded that these interests outweighed the privacy interests of the donor and granted an order to compel the deposition and production of documents by the donor. However, the Court noted that this conclusion did not automatically mean that the donor's identity must be revealed. The Court suggested that the attendees at the deposition could be limited and the transcript could refer to the donor as "John Doe". Further, the identities of the donor's family members were not to be disclosed.

Canada

The *AHR Act* allows offspring access to the identity of the donor only with the consent of the donor. Otherwise, only non-identifying information would be disclosed to the offspring, thereby preserving the donor's anonymity. In a scheme such as this, given that the donor is aware prior to donation that non-identifying information will be disclosed to the offspring and identifying information is only given to the offspring with the consent of the donor, it is unlikely that a donor could allege a breach of his or her right to privacy. However, what would the human rights implications be if legislation were enacted that retroactively abolished donor anonymity? Would a donor be able to claim that such legislation infringed his or her right to privacy?

As mentioned above, there is no Canadian jurisprudence addressing the privacy rights of donors of reproductive material. A review of the general principles of s. 7 and s. 8 of the *Charter* reveals that both the liberty and the security of the person interests may be relevant.[183]

The SCC has recognized that the liberty interest under s. 7 encompasses both the right to physical liberty and the right to make fundamental personal decisions without state interference.[184] The scope of this right to privacy respecting personal decisions is not broadly defined, and is limited to those decisions that "implicate basic choices going to the core of what it means to enjoy individual dignity and independence."[185]

The key question is if legislation were enacted that retroactively required the disclosure of the identity of gamete donors, would the court protect donor's anonymity by characterizing the decision to donate anonymously as a fundamental personal decision thereby attracting *Charter* protection?

---

[183] It is likely that as of January 1, 2004 the federal *Personal Information Protection and Electronic Documents Act* (PIPEDA) would also apply to fertility clinics collecting and retaining personal information about donors, except in the province of Quebec. Quebec has been exempted from the application of PIPEDA because it has substantially similar legislation in place, namely *An Act Respecting the Protection of Personal Information in the Private Sector*.

[184] *Morgentaler*, *supra* note 60; *B. (R.)*, *supra* note 63; *Godbout*, *supra* note 63; *Blencoe*, *supra* note 63.

[185] *Godbout*, *ibid.* at para. 66; *Blencoe*, *ibid.* at para. 54.

The case law respecting reproductive autonomy provides a useful analogy to determine whether the decision to donate reproductive material should be considered a fundamental personal decision worthy of protection. In *Morgentaler*, although the majority of the SCC decided the case on other grounds, Wilson J., writing on her own behalf, recognized that the decision to have an abortion was a fundamental personal decision that fell within the scope of the liberty interest. The American jurisprudence also deems decisions relating to reproduction as ones deserving of special protection. Although no case law exists on point, the jurisprudence that is available suggests that the interference by the state in the donor's personal autonomy in deciding to donate reproductive material could be considered to be a decision deserving the status of a fundamental personal decision.

A donor's right to security of the person may also be engaged if legislation were passed that allowed the disclosure of a donor's identity without his or her consent. The SCC has recognized that one's security of the person includes psychological integrity. As noted above, the state action "must have a serious and profound effect on a person's psychological integrity."[186]

Sperm donors are thoroughly screened and tested and generally provide sperm banks with multiple donations. Consequently, sperm donors are often a 'biological parent' to several offspring. If offspring were entitled to access the identity of the donor without consent, the donor could suffer some anxiety. Further, it could have significant emotional effects on the donor's family, as well as potential economic implications for the donor if the offspring or their social parent demanded child support.

It is difficult to predict whether a court would find that a donor's right to security of the person is engaged absent a legislative scheme eliminating the anonymous donation scheme. Several factors would need to be considered, for example, whether such a scheme would be put in effect retroactively.

If legislation were enacted that retroactively compelled the disclosure of the identity of donors to third parties, s. 8 of the *Charter*, which protects against unreasonable search and seizure, may also be engaged. The purpose of s. 8 is to protect individuals from unjustified state intrusions upon their privacy.[187] Two primary issues are examined in a s. 8 analysis. First, does the party claiming a s. 8 violation have a reasonable expectation of privacy? Second, is the governmental interference in that expectation of privacy reasonable?

Expectations of privacy arise in different circumstances. However, with respect to personal information, the SCC has recognized that a person may have a reasonable expectation of privacy in information.[188] In *R. v. Plant*, Sopinka J., for the majority, stated:

> In fostering the underlying values of dignity, integrity and autonomy, it is fitting that s. 8 of the *Charter* should seek to protect a biographical core of personal information which individuals in a free and democratic society would wish to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individuals.[189]

Clearly, any state action that retroactively required disclosure of an individual's identity as a donor of reproductive material to the resultant offspring would engage s. 8 of the *Charter*.

2.5.6 Conclusion

From the above discussion, it is apparent that the interests of children born as a result of AHR and the interests of donors of reproductive material are inter-related and have the potential to conflict. As such, an appropriate balance must be struck between the interests of these parties so as to maximize the benefits of AHR and minimize the possible negative implications of AHR.

---

[186] *Supra* note 63 at para. 60.

[187] *Hunter v. Southam*, [1984] 2 S.C.R. 145.

[188] *R. v. Dyment*, [1988] 2 S.C.R. 417.

[189] *R. v. Plant*, [1993] 3 S.C.R. 281 at 293.

2.6 Issue 3: The Status of *In vitro* Embryos

The medical, physical and emotional costs of undergoing IVF treatment are high. Frequently, in order to reduce some of these costs, a number of eggs are surgically retrieved from a woman undergoing treatment and fertilized. However, due to the risks of multiple pregnancies, only a few of the resulting *in vitro* embryos may be transferred into the woman. As discussed earlier, the remaining embryos are generally cryopreserved or "frozen" for future use.[190] To date in Canada, it is estimated that there are over 15,000 frozen *in vitro* embryos in storage across the country.[191] Unfortunately, disagreements can occur over the fate of these frozen embryos, particularly after a couple separates or one partner dies.

In this section, the human rights issues relating to *in vitro* embryos will be examined from different perspectives. First, the position of the donors of reproductive material will be addressed. Second, the perspective of the *in vitro* embryo itself will be discussed.

2.6.1 The Rights of Donors of Reproductive Material and Recipient Couples vis-à-vis a Frozen *In vitro* Embryo

As discussed above, individuals or couples seek out AHR services for a number of reasons. Sometimes both partners are unable to donate reproductive material to contribute to the resultant *in vitro* embryo, other times only one member of a couple can donate reproductive material and still in other circumstances both are able to donate reproductive material to create the resultant *in vitro* embryo. Consequently, a number of situations arise. First, there could be three separate parties involved in the creation of an *in vitro* embryo – two donors of reproductive material and a recipient individual or couple. Second, there could be two separate parties involved – one donor of reproductive material and a recipient couple, one member of the couple who will also donate reproductive material. Finally, there could be only the couple involved in a situation where the couple are both are able to donate their own reproductive material, but simply require AHR services to achieve a successful pregnancy.

To date, there is no case law in Canada respecting disputes between private parties over frozen *in vitro* embryos in relation to any of the above scenarios. However, given the large number of *in vitro* embryos currently in storage in Canada, it is foreseeable that a court could be asked to resolve such a dispute. In addition, there is no jurisprudence respecting the interference of a state with the rights of progenitors, which would more directly engage traditional human rights instruments that regulate the relationship between the state and its citizens.

U.S.

The American jurisprudence relating to disputes between private parties over *in vitro* embryos is varied. Some resolutions of these disputes are based on principles of contract law, while others employ a balancing test between private parties that largely centres on the concept of reproductive or procreational autonomy, namely the right to procreate of one party versus the right not to procreate of the other.

In *Davis v. Davis*,[192] both parties asserted their respective right to procreate and not to procreate based on their constitutional rights to liberty and privacy. In response, the Supreme Court of Tennessee formulated a test whereby the right to procreational autonomy of each party would be balanced. The Court concluded that in most cases, the party seeking to avoid procreation should prevail. However, if the party claiming the right to procreate seeks the frozen *in vitro* embryos for personal use and can demonstrate that he or she does not have any other "reasonable means" of pursuing parenthood, the Court may favour the right to procreate.[193]

Essentially, the Court concluded that when a dispute arises over the disposition of frozen *in vitro* embryos, the prior wishes of the donors as expressed in any prior agreement should stand. However, if a prior agreement does not exist, the balancing test should be employed.[194]

---

[190] Cryopreservation is the process by which embryos are frozen indefinitely in liquid nitrogen. For an explanation of cryopreservation see K. LaGatta, "The Frozen Embryo Debate Heats Up: A Call for Federal Regulation and Legislation" (2002) 4 Fl. Coastal L.J. 99.

[191] F. Baylis, et al., "Cryopreserved Human Embryos in Canada and their Availability for Research" (2003) 25(12) Canadian Journal of Obstetrics and Gynaecology 1026.

[192] 842 S.W. 2d 588 (Supreme Court of Tennessee 1992). Leave to appeal to U.S. Supreme Court refused.

[193] *Ibid.* at 604.

The Court's use of the 'right to procreate' versus the 'right not to procreate' to resolve this dispute is curious given that the rights found in the U.S. Constitution apply to the interaction between the state and its citizens rather than as between private parties. The Court's balancing of the parties' separate 'interests' in procreating or not procreating appears legitimate, but to use 'rights' language without clarifying the application of the Constitution is confusing.

Although the balancing test developed in *Davis* has been widely accepted, the U.S. courts have inconsistently adhered to prior disposition agreements between couples. For instance, in *Kass v. Kass*,[195] Mrs. Kass sought 'custody' of the couple's frozen embryos for implantation, while Mr. Kass sought to enforce their disposition agreement, which stated that if a dispute arose, the embryos would be donated for research purposes. The Court of Appeals for New York agreed with the Court in Davis and held that in general, prior agreements should be upheld in order to maximize procreative liberty by allowing the sperm and egg donors the authority to determine disposition, which the Court found to be a "deeply personal life choice."[196]

In contrast, in *A.Z. v. B.Z.*,[197] the Supreme Judicial Court of Massachusetts found that a disposition agreement was not binding for several reasons, most notably because it found that the agreement likely did not represent the intent of the donors given the circumstances upon which it was signed. More significantly, the Court stated that agreements requiring "forced procreation" should not be enforceable due to public policy concerns.[198]

A similar result was reached in *J.B. v. M.B.*,[199] where the husband alleged that the couple had entered into an oral agreement to donate any excess *in vitro* embryos to an infertile couple. The Supreme Court of New Jersey held that if a couple wished to enter into a prior agreement a clear written statement of intention was necessary. Given that an enforceable contract did not exist, the Court used the balancing test formulated in Davis. The Court found that since the husband was already a father and was still able to father children, the realization of his right to procreate was not lost. However, the wife's right not to procreate would be permanently extinguished if the *in vitro* embryos were donated to an infertile couple.[200] The Court refused to force the wife to "become a biological parent against her will."[201] Consequently, the wife's right not to procreate prevailed.

Canada

The rights of the donors of reproductive material in relation to the frozen *in vitro* embryos created using their reproductive material may be largely dependent on the status or classification of the *in vitro* embryo. For instance, in the event that frozen *in vitro* embryos were seized by the Crown,[202] and *in vitro* embryos were classified as the "property" of their progenitors, the right to the enjoyment of property and the right not to be deprived of such property except by due process of law contained in the *Canadian Bill of Rights*,[203] would likely be engaged.[204]

Discussion

The disputes discussed above, were in relation to *in vitro* embryos that were created with the reproductive material of the couple that wished to use the *in vitro* embryo for their own use at one point in time.

No case law exists in respect of the situation where a dispute arose over *in vitro* embryos that were not created with reproductive material of the couple that intended to use the resultant *in vitro* embryo. Presumably, the dispute between the couple whose reproductive material was not used to create the *in vitro* embryo would be resolved in the same fashion as in the case where the reproductive material used to create the *in vitro* embryo was from the couple that intended to use the *in vitro* embryo.

---

[194] *Ibid.*

[195] 696 N.E. 2d 174 (N.Y. Court of Appeals 1998).

[196] *Ibid.* at 180.

[197] 725 N.E. 2d 1051 (Supreme Judicial Court of Massachusetts 2000).

[198] *Ibid.* at 1058.

[199] 751 A. 2d 613 (N.J. Super. Ct. App. Div. 2000), aff'd as modified, 783 A. 2d 707 (N.J. 2001).

[200] *Ibid.* at 717.

[201] *Ibid.*

[202] A "seizure by the Crown" is contemplated in clause 50(1) of the *Assisted Human Reproduction Act* whereby an inspector designated under the Act could may seize material, defined as "an embryo or part of one, a fœtus or part of one or any human reproductive material outside the body of a human being, or any other thing", if the inspector has reasonable grounds to believe that the Act has been contravened. Pursuant to clause 50(2), an inspector may direct that the seized material be kept stored in the place where it was seized or removed to another place.

[203] S.C. 1960, c. 44, s. 1(a).

[204] For the latest decision by the SCC respecting the *Canadian Bill of Rights*, see: *Authorson v. Canada (Attorney General)*, [2003] SCC 39.

With respect to the application of traditional human rights instruments to disputes over *in vitro* embryos, if the state were to attempt to regulate or control the use of the *in vitro* embryo created with the couple's reproductive material, the reproductive autonomy rights of the couple would surely be engaged. In addition, in a situation where the *in vitro* embryo was not created with the reproductive material of the couple that intended to use it, it is likely that the couple's right to reproductive autonomy would also be engaged if the state attempted to regulate or control the use of the *in vitro* embryo, regardless of the fact that either one or both of the couple would not be the genetic parents of the *in vitro* embryo.

A final question remains with respect to the rights of the donors of reproductive material who are not the recipient couple. How would a dispute be resolved as between either a sperm donor or an ovum donor and the recipient couple who used the donated reproductive material to create an *in vitro* embryo for their own use? Once again, such a dispute would be between private parties and therefore, traditional human rights instruments would not be directly applicable. It is likely that a resolution to such a dispute would largely be dependant on the consent given by the donor and the contractual arrangement between the donor and the recipient couple, or more likely between the donor and the clinic or medical institution involved.

Conclusion

Disputes over dispositional authority of *in vitro* embryos clearly involve a balancing of interests between the donors. However, human rights instruments, such as the *Charter*, which govern the relationship between the state and its citizens, would not be applicable to purely private disputes between donors. Although, if the state became involved in regulating AHR activities and resulting disputes over *in vitro* embryos, traditional human rights instruments would then be engaged. From the limited American case law, it appears that the interests of one party not to procreate generally prevails over the interests of the other party to procreate, in the absence of a prior agreement, and sometimes notwithstanding a prior agreement. If a dispute over frozen *in vitro* embryos was to occur in Canada, our courts could look to the American model to fashion a similar test to assist in balancing the competing interests involved or develop a uniquely Canadian approach.

2.6.2 The Legal Status of the *In vitro* Embryo

With respect to the *in vitro* embryo, the first issue that must be addressed is whether or not it has any rights. To determine whether human rights, most importantly the right to life, apply to an *in vitro* embryo, the legal status of the *in vitro* embryo must be examined. There are three viewpoints with respect to the status of the *in vitro* embryo: (1) the embryo as property, (2) the embryo as a sui generis entity deserving special protection, and (3) the embryo as a person.[205]

2.6.2.1 The In vitro Embryo as Property

The property approach considers the *in vitro* embryo as the property of the two individuals whose reproductive material was used to create it or those individuals or couples to whom the *in vitro* embryo was donated for reproductive purposes. Under this approach, principles of ownership would govern the use or disposition of the *in vitro* embryo.[206] Essentially, a property approach would create a scheme of joint authority between either the egg and sperm donor or the recipient couple over the *in vitro* embryo.[207]

Several reports regarding the ethical, legal and social issues pertaining to AHR have rejected the notion that *in vitro* embryos should be treated as property. For instance, in the Report prepared by the Royal Commission on New Reproductive Technologies, the Commission rejected the notion that property concepts be used to determine the disposition of *in vitro* embryos. The Report stated:

---

[205] E.A. Pitrolo, "The Birds, The Bees, And the Deep Freeze: Is there International Consensus in the Debate Over Assisted Reproductive Technologies?" (1996) 19 Hous. J. Int'l L. 147 at 200; J.F. Daar, "Regulating Reproductive Technologies: Panacea or Paper Tiger?" (1997) 34 Hous. L. Rev. 609 at 634; S. Fiandaca, "*In vitro* Fertilization and Embryos: The Need for International Guidelines" (1998) 8 Alb. L.J. Sci. & Tech. 337 at 360; L. Brandimarte, "Sperm Plus Egg Equals One "Boiled" Debate: Kass v. Kass and The Fate of the Frozen Pre-Zygotes" (2000) 17 N.Y.L. Sch. J. Hum. Rts. 767 at 775; L.B. Andrews, "Regulating Reproductive Technologies" (2000) 21 J. Legal Med. 35.

[206] K.H. Windsor, "Disposition of Cryopreserved Preembryos After Divorce" (2003) 88 Iowa L. Rev. 1001 at 1010.

[207] *Ibid.*

> [I]n the Commission's view, reproductive material should never be characterized as property, because terms such as "ownership" and "property" suggest that human zygotes can be treated as objects, which is contrary to principles such as respect for human life and dignity and non-commercialization of reproduction. The Commission therefore believes that the complex issues of control and decisional authority with respect to human zygotes must be addressed in a conceptual framework that makes it clear that they are not "property".[208]

Further, the Commission outlined several potential problems with treating *in vitro* embryos as property. The Commission noted:

> A pure property law regime would give the "owners" of zygotes not only a right of control, but also all the other standard incidents of ownership. For example, owners of property are generally allowed to give property away or sell it, bequeath it to inheritors, destroy it or experiment on it, store it, and share in the profits of research on it. These implications of a pure property law regime for embryos are clearly unacceptable.[209]

Interestingly, many of the activities that are characteristics of a pure property regime identified by the Commission, such as having the authority to destroy, store, inherit or donate an *in vitro* embryo are currently permitted in many countries.

The Waller Report, prepared for the Australian state of Victoria, stated that, "the committee does not regard the couple whose embryo is stored as owning or having dominion over that embryo."[210]

A similar sentiment was reflected in the Demack Report, commissioned by the Australian state of Queensland. The Committee stated that, "it is not acceptable to think of the donors of gametes as having some right of ownership of the gamete."[211]

Finally, the U.K.'s Warnock Committee stated the following with respect to the property approach:

> The concept of ownership of human embryos seems to us to be undesirable. We recommend that legislation be enacted to ensure there is no right of ownership in a human embryo. Nevertheless, the couple who have stored an embryo for their use should be recognised as having rights to the use and disposal of the embryo, although these rights ought to be subject to limitation.[212]

U.S.

Generally, the disposition of *in vitro* embryos by the property approach has not found favour in the U.S. Courts. Although, in a motion to dismiss in *York v. Jones*,[213] which was eventually settled out of court, the Court did appear to accept this approach. In this case, the couple underwent IVF at the defendant clinic in Virginia, with no success. Thereafter, they moved to California and attempted to have their last frozen *in vitro* embryo transferred to a clinic in California. The defendant clinic refused to comply with the request. The couple sued the clinic on the basis of breach of contract and detinue, a cause of action specifically related to property. They had signed a cryopreservation agreement with the Virginia clinic, which gave responsibility for embryo disposition to the couple and also provided that if the couple divorced, the rules of property settlements would govern the disposition of the embryos. The agreement also stated that the clinic would only store the *in vitro* embryos while the couple was active in the IVF program.

---

[208] *Supra* note 9 at 597.

[209] *Ibid.* at 627.

[210] Victoria, Committee to Consider the Social, Ethical and Legal Issues arising from *In vitro* Fertilization, (The Waller Committee), Report on the Disposition of Embryos Produced by *In vitro* Fertilization, 1984, at 27.

[211] Queensland, Special Committee (The Demack Report), Report to Enquire into the Laws Relating to Artificial Insemination, *In vitro* Fertilization and Other Related Matters, 1984, at 77.

[212] United Kingdom, Committee of Inquiry into Human Fertilisation and Embryology (The Warnock Committee), Report of the Committee of Inquiry into Human Fertilisation and Embryology, 1984, at 56.

[213] 717 F. Supp. 421 (U.S. Dist. Ct. Eastern Dist. Virginia 1989).

The Court took note of the consistent reference to the *in vitro* embryo in the agreement as the "property" of the couple and found that the agreement created a bailment relationship between the couple and the clinic.[214] Given that in a bailment situation, an action in detinue arises automatically upon a demand for the property and a corresponding refusal, the Court denied the motion to dismiss on the basis that the causes of action were proper claims.[215]

The Court employed the property approach in *York v. Jones* so as to allow the egg and sperm donors the dispositional authority over their *in vitro* embryo as against a third party. However, this decision does not assist in disputes where it is the egg and sperm donor who cannot agree on the disposition of their *in vitro* embryo.

This property approach taken in *York v. Jones* is in contrast to *Moore v. The Regents of the University of California*,[216] one of the most well known cases respecting one's property interest in his or her body. In this case, the Supreme Court of California was asked to determine whether Mr. Moore had any property rights in his bodily substances, including sperm, tissues and organs that were removed by or supplied to his physician during a course of treatment for leukemia.

Two issues were before the Court. First, whether the physician breached his fiduciary duty to disclose all relevant information prior to obtaining Mr. Moore's consent. And second, whether the defendants committed the tort of conversion by taking Mr. Moore's property (i.e. his cells) and converting them. The Court had no difficulty in concluding that the physician had breached his duty of disclosure to Mr. Moore. However, the question of conversion raised several issues.

Although the majority conceded that Moore might have "some right to control the use of excised cells,"[217] it held that Moore's rights were better protected by the requirement of an informed consent prior to any medical procedure. Based on their concern regarding the access to such materials for research, the majority held that Mr. Moore could not be said to have any 'property' or 'ownership' rights left in the cells for the purpose of the tort of conversion. However, the majority noted that "we do not purport to hold that excised cells can never be property for any purpose whatsoever."[218]

It is apparent that public policy considerations played a large role in this decision. In particular, the Court was clearly cognizant of the potential negative effect on scientists' access to the necessary raw materials for research if Mr. Moore's tort claim was successful. The constraint on research would have been onerous. Researchers would have to obtain consent from the prior 'owner' of the material and would possibly have to contract with the prior 'owner' to use the material in research and thereafter compensate the prior 'owner' if the research was profitable.[219] Consequently, in the majority's view, the case was best dealt with by assigning liability based on the physician's existing disclosure obligations.

Clearly, employing a pure property approach towards disputes over frozen *in vitro* embryos is fraught with difficulties, including the application of family law respecting the division of property to frozen *in vitro* embryos upon the dissolution of a relationship and the engagement of succession law if one of the donors predeceases implantation. Further, if the property approach was accepted, as a form of pure property, *in vitro* embryos could, and would most likely become the subject of commercial transactions.

2.6.2.2 The *In vitro* Embryo as *Sui Generis*

The view that the *in vitro* embryo is *sui generis* or unique stems from the belief that an *in vitro* embryo is unique and deserves greater respect than other human tissues or organs because of its potential to develop into a human being. However, given that it has not yet achieved of the status of a human being, it occupies an interim status between property and personhood.[220]

This view has been accepted by a number of committees set up to explore issues related to AHR. For example, Canada's Royal Commission on New Reproductive

---

[214] *Ibid.* at 425.

[215] *Ibid.* at 427.

[216] 271 Cal. Rep. 146 (Supreme Court of California 1990).

[217] *Ibid.* at 158.

[218] *Ibid.* at 160.

[219] *Ibid.* at 154 – 155.

[220] Daar, *supra* note 205 at 634.

Technologies stated that "[l]egal rules relating to the zygote and embryo should be designed to ensure that they are treated with respect as a form of potential human life."[221]

The Waller Commission of Victoria and the New South Wales Law Reform Commission have also adopted this interim position. The Waller Commission noted that although an *in vitro* embryo is a unique entity, it is not a person.[222] The New South Wales Law Reform Commission stated that, "it accepts the special status of the embryo, and recognises that its handling – whether for implantation, storage or for research should be a matter of special consideration."[223]

In its discussion on research on embryos, the U.K. Warnock Committee has also stated that, "the embryo of the human species ought to have a special status."[224]

International Law

The only international instrument with a specific reference to *in vitro* embryos is the Council of Europe's Convention on Human Rights and Biomedicine, to which Canada is not a party.[225] This Convention contains a specific provision respecting research on *in vitro* embryos, a topic that will be explored more fully in the following chapter. Article 18 states:

1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.[226]

The existence of this provision, and its placement following two articles that address the protection of persons undergoing research is noteworthy. It could be argued that if *in vitro* embryos had the status of personhood, there would have been no need to have a separate provision to protect them. However, the inclusion of a specific provision to protect *in vitro* embryos is an indication that although *in vitro* embryos are not persons, their potential to become a human being affords them additional protections, that are traditionally not afforded to property.

U.S.

One of the leading cases involving a dispute over *in vitro* embryos between former partners is *Davis v. Davis*,[227] which was discussed above. At trial, the court accorded the *in vitro* embryo the status of personhood and awarded custody to Mrs. Davis for implantation, which was her intention at the time. The case was appealed and by the time it reached the Tennessee Supreme Court, the couple was divorced and Mrs. Davis wanted them to be donated to an infertile couple, while Mr. Davis wanted to dispose of the *in vitro* embryos.

Having no legislation or disposition agreement to guide it, the Tennessee Supreme Court examined the legal status of a frozen *in vitro* embryo. The Court found that the *in vitro* embryo should not be treated as a form of property nor should it be granted the legal status of a person. Rather, *in vitro* embryos should occupy a special category "that entitles them to a special respect because of their potential for human life."[228] With respect to the interests of the egg and sperm donor, the Court found that they do not have a "true property interest" but rather "an interest in the nature of ownership, to the extent that they have decision-making authority concerning disposition of the preembryos, within the scope of policy set by law."[229]

This issue of donated gametes has been considered in the context of a deceased's estate. In *Hecht v. Superior Court of Los Angeles County*,[230] the Court was asked to determine whether the deceased's girlfriend (Ms. Hecht) or his adult children controlled his stored sperm. Prior to his death, the deceased deposited sperm with a sperm bank. A storage agreement was executed providing that, in the event of his death, the sperm would continue to be stored or released either to the executor of his estate, Ms. Hecht or her physician. The deceased's will assigned all "right, title, and interest" in the stored sperm to Ms. Hecht.

---

[221] *Supra* note 9 at 627.
[222] *Supra* note 210 at 27.
[223] New South Wales, Law Reform Commission, Report 58, Artificial Conception Report 2 – *In vitro* Fertilization, (1987) at 27.
[224] *Supra* note 212 at 63.
[225] *Supra* note 88. Canada is not a party to this Convention.
[226] *Ibid.* at Article 18.
[227] *Supra* note 192.
[228] *Ibid.* at 596.
[229] *Ibid.* at 597. The term 'preembryo' is often referred to describe the period from fertilization up to 14 days after fertilization.
[230] 20 Cal. Rptr. 2d 275 (Ct. App. 1993).

The probate court ordered the destruction of the sperm. However, Ms. Hecht appealed to the Court of Appeal of California, which rejected any reliance on Moore to argue that the deceased had no ownership or possessory interest in his sperm.[231] Instead, the Court, following the decision in Davis, found that the deceased had an interest in his stored sperm, although not governed by "the general law of personal property, [s]perm occupies an interim category that entitles them to special respect because of their potential for human life."[232]

Therefore, the Court held that at the time of death, the deceased had an interest in the nature of ownership, so that he had decision-making authority as to the disposition of the sperm within the scope of public policy set by law.[233] In coming to its conclusion, the Court relied on the American Fertility Society's view that it should be left up to the donors to decide the disposition of gametes and concepti.[234] The Court's decision was also influenced by the American Fertility Society's position respecting *in vitro* embryos which states that they deserve respect greater than that accorded to human tissue, but not the same degree of respect accorded to actual persons.[235]

Three years later, Ms. Hecht was forced to petition the Court of Appeal again in order to secure the release of all of her former partner's stored sperm.[236] This dispute arose out of the property settlement reached by the parties. The Court reaffirmed its earlier position that genetic material is a unique form of "property" and is not subject to division among parties that is inconsistent with the express wishes of the deceased. The Court stated that "[a] man's sperm or a woman's ova or a couple's embryos are not the same as a quarter of land, a cache of cash, or a favorite limousine. Rules appropriate to the disposition of the latter are not necessarily appropriate for the former."[237] As a result, the intent of the sperm donor, even when deceased, controlled the disposition and use of the sperm.[238]

France

The French Courts have also grappled with the legal status of stored sperm and *in vitro* embryos. *In Parapalaix c. Centre d'etude et de Conservation du Sperme,*[239] the French Court characterized sperm as the "seed of life," which is tied to the fundamental liberty of a human being to conceive or not to conceive.[240] As such, the Court concluded that the fate of stored sperm should be decided based on the donor's intent.

Almost a decade later, the French court was faced with the question of the status of *in vitro* embryos in *Mme. O. c. CECOS.*[241] In this case, a couple had *in vitro* embryos stored at the defendant facility. Before transfer, the husband passed away and the facility refused to allow Mme. O to undergo transfer of the *in vitro* embryo. The High Court held that a fertilized embryo was "not a legal entity with respect to the parents."[242] Moreover, *in vitro* embryos were not the joint property of the couple.[243]

At present, the recognition of the *in vitro* embryo as *sui generis* appears to be the most accepted view in the academic literature. This interim position between pure property and full personhood status, according to various academics, accords an appropriate amount of respect to an entity that has the potential to be a human being.[244]

2.6.2.3 The *In vitro* Embryo as a Person

Finally, there is the view that the embryo is a person with full moral standing and an inviolable right to life. For some, this status applies from the moment of conception. For others, this status applies at some specific developmental stage (e.g., appearance of the primitive streak at the 15th day) in which case the embryo achieves full moral standing not at the moment of conception, but when it reaches the specific developmental stage.

---

[231] *Ibid.* at 279.
[232] *Ibid.* at 281.
[233] *Ibid.* at 283.
[234] *Ibid.* at 282.
[235] *Ibid.* at 282.
[236] *Hecht v. Superior Court*, 59 Cal. Rptr. 2d 222 (Court of Appeal of California 1997).
[237] *Ibid.* at 226.
[238] *Ibid.* at 226 – 227.
[239] *Supra* note 42.
[240] *Supra* note 43 at 686.
[241] T.G.I. Rennes, June 30, 1993, J.C.P. 1994, II, 22250, 169.
[242] *Ibid.* at 169.
[243] *Supra* note 43 at 690.
[244] J. Coleman, "Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures" (1996) 27 Pac. L. J. 1331 at 1343.

American Convention on Human Rights

The Organization of American States ("OAS") is a regional organization with membership from South and Central America, the Caribbean, the U.S. and Canada. It is a regional agency within the meaning of Article 52 of the United Nations *Charter*.

In 1969, the OAS Conference on Human Rights adopted the *American Convention on Human Rights* ("*Convention*").[245] The *Convention* is the only international human rights instrument that expressly contemplates protection of the fœtus. Although the U.S. is a signatory, it has not ratified the *Convention*. Canada has neither signed nor ratified the *Convention*.

Article 4(1) of the *Convention* provides:

> Article 4.1
>
> Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life.

In Article 4(1), the protection of the unborn is qualified by the words "in general." The *Travaux Préparatoires* to the *Convention* indicate that there was strong opposition by some State delegations to a proposal to delete the phrase "in general." It was felt that the right to lawful abortion, which existed in some countries, should not be compromised. The great majority of States were of the view however, that Article 4 should protect the life of the unborn and many of the OAS member States view abortion as a crime.[246]

In contrast to the *Convention*, the *American Declaration of the Rights and Duties of Man* protects the right to life without reference to the moment of conception. The Commission concluded in the Baby Boy case,[247] which challenged U.S. abortion laws, that the fœtus was not protected by the right to life in the *Declaration*, which does not contain the phrase "in general from the moment of conception." Although Article 4 was not at issue, since the U.S. had not ratified the *Convention*, the Commission nevertheless discussed the meaning of the right to life under that provision and the majority noted that the phrase, "in general from the moment of conception" represented a compromise between the pro and anti-abortion positions of OAS member states.[248]

Mexico, upon ratification of the *Convention*, filed an interpretive declaration to the effect that the expression "in general" does not constitute an obligation to adopt, or keep in force, legislation to protect life from the "moment of conception," since this matter falls within the domain reserved to the States.[249]

There is no Canadian legislation that guarantees an embryo or fœtus the right to life. In most western countries, the prevailing view of the moral status of the embryo is that it is *sui generis*, i.e., deserving of respect. Its status is not viewed as equivalent to that of a child, because of the lack of developmental individualism and sentience, as well as the extremely high natural mortality rate of an embryo.

In Canada, the court has held that an *in utero* embryo and a fœtus are not persons under the law and thus have no legal rights. However, once the fœtus is born alive, his or her legal rights crystallize and for certain purposes, such as tort law, the law may recognize that the child existed before birth.

Because the *in utero* embryo and fœtus have no legal rights, they are not considered to have a right to life. However, the state's interest in the fœtus as a potential human being may increase as it develops within the womb. Once the fœtus is viable, which is sometime in the second trimester of the pregnancy (see Justice Wilson in *Morgentaler*), the state may be able to justify interfering with the pregnant woman's rights in order to protect the fœtus and the health of the mother.

---

[245] *American Convention on Human Rights*, O.A.S. treaty Series No. 36, 1144 U.N.T.S. 123 entered into force July 18, 1978, *reprinted in* Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82doc.6rev.1 at 25 (1992) http://www.oas.org/juridico/english/treaties.html

[246]

[247] http://www.cidh.org/annualrep/80.81eng/usa2141.htm

[248] *Ibid.*

[249] http://www.oas.org/juridico/english/treaties.html

Based on current case law, an *in vitro* embryo existing as it does outside a woman's body would likely be assigned the same non-person status as an *in utero* embryo and fœtus by a court, and thus be found not to possess any legal rights until after birth. The court would likely find that an *in vitro* embryo does not have a right to life.

Australia

The status of the fœtus in Australia is similar to other common law jurisdictions. *In the Marriage of: F. Husband and F. Wife Injunctions*,[250] the Court held that a "fœtus has no legal personality and cannot have a right of its own until it is born and has a separate existence from its mother."[251] Similar to Canada, the Australian courts have recognized that the fœtus has a contingent interest in tort law. However, the interest only crystallizes once the fœtus is born alive.[252]

U.K.

The fate of frozen *in vitro* embryos has recently been addressed in a highly publicized case in the U.K.[253] Two women sought to use their frozen *in vitro* embryos against the wishes of their former partners, who had withdrawn their consent to the storage and use of the embryos. One of the arguments presented on behalf of the women was that the right to life pursuant to article 2 of the European *Convention for the Protection of Human Rights and Fundamental Freedoms*,[254] was applicable to the embryo. Although the claimants conceded that an *in vitro* embryo was not a human being, they argued that an *in vitro* embryo has "special status" deserving protection of a "qualified" right to life under article 2.[255] The Court reviewed the U.K. jurisprudence addressing the legal status of the fœtus, which states that a fœtus, at whichever stage of development, does not have an existence outside of its mother's body and therefore does not have a right to life. Given this case law, the Court found that an *in vitro* embryo also could not be considered to be a person.[256] Further, an *in vitro* embryo could not be considered to have a right to life or a "qualified" right to life.[257]

U.S.

In *Roe v. Wade*,[258] the U.S. Supreme Court held that the word "person" contained in the Fourteenth Amendment to the U.S. Constitution does not include the unborn.[259] However, the Court did recognize the state's interest in protecting the unborn. To this end, the Court formulated the 'trimester approach', which attempted to balance the privacy interests of the mother and the interest of the state in protecting the life of the unborn. Using this approach, during the first trimester of pregnancy, the state may not interfere with a woman's decision to undergo an abortion. However, by the third trimester, the state may interfere quite intensely to preserve the life of the fœtus.[260]

In 1992, the U.S. Supreme Court upheld the principles outlined in *Roe v. Wade* in *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[261] However, the trimester scheme was replaced by a standard of viability approach. The Court held that the state had a continuing interest in preserving life, which begins at conception and becomes compelling at the stage where the fœtus is viable. Prior to viability, the state may regulate abortion provided that it does not place "an undue burden" on a woman's right to choose to terminate her pregnancy. After the stage of viability, the state may regulate more strictly.[262]

Some U.S. states have passed legislation respecting AHR. However, Louisiana is the only state to grant personhood status to the *in vitro* embryo. In Louisiana, legislation exists that states that *in vitro* embryos are biological human beings entitled to the protections of a "juridical person."[263] Furthermore, as a juridical person, the *in vitro* embryo can sue and be sued. Accordingly, *in vitro* embryos are not the property of physicians, the IVF clinic or the gamete donors. However, the physician or the medical facility storing the *in vitro* embryo, are responsible for the safekeeping of the frozen *in vitro* embryo. The statute also states that *in vitro* embryos should not be intentionally destroyed and should be made available for adoption if the donors rescind their parental rights.[264]

---

[250] (1989) 13 Fam. L.R. 189 (Fam. Ct. of Australia).

[251] *Ibid.* at para. 31. This case reiterated the point made in *Attorney-General ex relation Kerr v. T.* (1983) 1 Qd R 404.

[252] *Watt v. Rama.* (1972) VR 353.

[253] *Evans v. Amicus Healthcare Ltd and others; Hadley v. Midland Fertility Services Ltd and others*, [2003] EWHC 2161 (Fam. Div.).

[254] As adopted in the U.K. *Human Rights Act 1998.*

[255] *Supra* note 253 at para. 174.

[256] *Ibid.* at para. 178.

[257] *Ibid.*

[258] *Supra* note 52.

[259] *Ibid.* at 158.

[260] *Ibid.* at 163.

[261] 505 U.S. 833 (U.S. S.C. 1992).

[262] In 2000, the U.S. Supreme Court reaffirmed the principles set out in *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey* in *Stenberg v. Carhart.* In this case, the narrow majority held that the state prohibition on partial birth abortions during the period of non-viability was an undue burden on the woman's right to choose to terminate pregnancy.

France

In *Mme P. c. La Grave Hôpital*,[265] a storage agreement was executed between a couple and the defendant hospital, which stated that both parties had to consent before implantation occurred. The husband died and the wife argued that the agreement should be disregarded because life began at conception and public policy considerations favoured the implantation of the *in vitro* embryo, a conceived life. The Court held that French law did not recognize frozen *in vitro* embryos as capable of possessing rights.[266] Accordingly, the Court ordered the destruction of the embryos.

Europe

The European Commission on Human Rights has addressed the right to life of the fœtus in two cases. In *X. v. U.K.*,[267] the applicant, a citizen of the U.K., attempted to obtain an injunction to prevent his wife from having an abortion. The U.K. court dismissed the application because an injunction could only be granted to protect a legal right. The Court held that a fœtus had no legal rights until it is born and had a separate existence from its mother. Further, the father had no legal right under U.K. law to prevent the mother from obtaining an abortion.

The father applied to the Commission contending that the U.K. law violated several articles of the *European Convention on Human Rights*, including article 2, which guarantees to "everyone" the right to life. With respect to the reference to "everyone" in article 2, the Commission noted that "both the general usage of the term 'everyone' ('toute personne') in the Convention…and the context in which this term is employed in Article 2…tend to support the view that it does not include the unborn."[268] With respect to whether "the right to life" applied to only the life of individuals already born or also includes the unborn life of the fœtus, the Commission noted the three available interpretations as: (1) that article 2 does not cover the fœtus at all; (2) that the fœtus has a "right to life," but with implied limitations; or (3) that there is an absolute "right to life" of the fœtus.[269]

The Commission concluded that recognizing the absolute right to life of a fœtus would be contrary to the object and purpose of the Convention.[270] However, it declined to conclude which of the remaining two interpretations was the correct one.

The Commission was faced with similar facts in *R.H. v. Norway*.[271] In this case, the Commission noted that the Austrian Constitutional Court had concluded that article 2 did not protect the unborn, while the German Federal Constitutional Court found that article 2 did protect unborn human beings.[272] Once again, the Commission declined to decide whether article 2 of the Convention protected the fœtus, but stated that it "will not exclude that in certain circumstances this may be the case notwithstanding that there is in the Contracting States a considerable divergence of views on whether or to what extent article 2 protects the unborn life."[273]

Germany

Germany has conferred human status on the *in vitro* embryo in its *Embryo Protection Act*.[274] In the *Act*, human dignity and the right to life are assigned to the human embryo from the moment of fertilization. Consequently, the *Act* prohibits the use of *in vitro* embryos for purposes other than their maintenance and survival.[275]

---

[263] La. Rev. Stat. Ann. [ss.] 9:121 – 9:133 (1991). For a discussion of the Louisiana law see : T.S. Jost, "Rights of Embryos and fœtus in Private Law" (2002) 50 Am. J. Comp. L. 633.

[264] *Ibid.*

[265] *CA Toulouse, August 18, 1994, J.C.P. 1995, II, 224072, 301.*

[266] *Supra* note 43 at 690.

[267] 13 May 1980, App. No. 8416/78.

[268] *Ibid.* at para. 9.

[269] *Ibid.* at para. 17.

[270] *Ibid.* at para. 21. See also B.E. Hernandez, "To Bear or Not to Bear: Reproductive Freedom as an International Human Right" (1991) 17 Brook. J. Int'l L. 309 at 333.

[271] 19 May 1992, App. No. 17004/90.

[272] *Ibid.* at para. 26.

[273] *Ibid.* at para. 25.

[274] *Embryo Protection Act* of 13 December 1990.

Canada

There is no Canadian jurisprudence addressing the legal status of an *in vitro* embryo. With the recent passing of the *Assisted Human Reproduction Act*, it is likely that the *Charter* will apply to certain AHR activities. The courts would likely look for guidance to the jurisprudence discussing the legal status of the fœtus and whether or not the right to life applies, as guaranteed by s. 7 of the *Charter*, as a starting point.

In *Borowski v. Attorney General of Canada*,[276] Mr. Borowski challenged the abortion provision then in place in the *Criminal Code* on the basis that it infringed the right to life of the fœtus under s. 7 of the *Charter*. The Saskatchewan Court of Appeal concluded that a fœtus is not a person in law. Further, the terms "everyone" in s. 7 and "every individual" in s. 15 of the *Charter* do not include a fœtus, and consequently, the *Charter* was inapplicable.

In *R. v. Demers*,[277] the claimant was convicted of several protest-related offences under the B.C. *Access to Abortion Services Act*. In addition to arguing that the legislation at issue infringed his right to freedom of expression under the *Charter*, Mr. Demers also claimed that the term "everyone" in s. 7 included an unborn fœtus. The B.C. Court of Appeal reviewed the Canadian jurisprudence regarding the legal status of the fœtus and held that "these cases leave no room for this court to entertain the constitutional argument advanced by Mr. Demers."[278] The Court concluded that the right to life does not extend to an unborn fœtus.

Although the SCC has never directly addressed the question put forth in *Borowski* or *Demers*, it has addressed foetal rights in the child-welfare context and in the criminal context.

In *Tremblay v. Daigle*,[279] the legal status of the fœtus was examined under the Quebec *Charter of Human Rights and Freedoms*. In this case, the father of an unborn child attempted to prevent the mother from having an abortion by seeking an injunction. The SCC concluded that a fœtus was not included in the term "human being" found in the Quebec *Charter*.[280] In order to have rights, a fœtus must be born alive.[281]

The Court also had the opportunity to discuss the legal status of the fœtus in *Winnipeg Child and Family Services v. G.(D.F.)*[282] *In this case, the SCC was asked whether tort law or parens patriae* jurisdiction should be extended to allow a court to order the detention and treatment of a pregnant woman to prevent harm to her fœtus. The majority cited the general principle that in Canadian law a fœtus is not recognized as a legal person capable of possessing rights.[283] This principle applied to "all aspects of the law."[284] The Court did recognize that once a child was born alive, the law might acknowledge that the child existed before its birth for limited purposes. However, "any right or interest the fœtus may have remains inchoate and incomplete until the child's birth."[285]

In *R. v. Sullivan*,[286] the accused midwives were charged with criminal negligence causing death to a person after a baby they were attempting to deliver died while still in the birth canal. The Court was asked to determine whether the fœtus in the birth canal was a person within the meaning of the Criminal Code provision in question. The Court found that the fœtus was not a "human being" or "person" and consequently, the accused could not be convicted of the above-mentioned offence.

---

[275] Goethe-Institut Zentrale, http://www.goethe.de/kug/buw/fut/thm/en37295.htm (date accessed: November 26, 2003); Pitrolo, *supra* note 206 at 190.

[276] (1987), 39 D.L.R. (4th) 731 (Sask. C.A.). Leave to the SCC was granted to this case, but the SCC held that the appeal was moot and that the appellant no longer had standing. Consequently, the SCC decision that it should not exercise its discretion to hear the case.

[277] [2003] B.C.J. No. 75 (B.C.C.A.) leave to S.C.C. denied [2003] S.C.C.A. No 103.

[278] *Ibid.* at para. 23.

[279] [1989] 2 S.C.R. 530.

[280] *Ibid.* at para. 72.

[281] See also M. Shaffer, "Foetal Rights and the Regulation of Abortion" (1994) 39 McGill L.J. 58.

[282] *Supra* note 65.

[283] *Ibid.* at para 11.

[284] *Ibid.* at para 11.

[285] *Ibid.* at para 15.

[286] [1991] 1 S.C.R. 489.

In sum, at the present time in Canada, the law does not recognize a fœtus as a legal person.[287] The result is that a fœtus does not enjoy the human rights protections guaranteed by the *Charter*.

Discussion

To best understand the issues related to the status of an *in vitro* embryo in Canada, one could consider that the building blocks of life exist on a continuum of development. In the AHR context, the sperm and the egg are at one end of the continuum, fusion of the sperm and egg results in an *in vitro* embryo that exists outside of its progenitors, then after transfer and implantation the embryo develops into a fœtus that would not be viable outside the body of a woman, then to a fœtus that would be viable outside the body of a woman, and finally to a baby.

The fundamental problem with the argument that *in vitro* embryos should be accorded personhood status, with all the accompanying legal rights, most importantly the right to life, is that it assigns more protection to the *in vitro* embryo than Canadian and other courts have guaranteed a fœtus.[288] If an *in vitro* embryo were assigned personhood status and consequently the right to life, one could argue that the natural conclusion would be that the *in vitro* embryo has the right to be transferred. However, upon implantation under the laws of most jurisdictions, including Canada, a fœtus that would not be viable outside the body of a woman could be aborted with very little state interference.

In the Canadian context, if one accepts this continuum of development and the applicable jurisprudence discussing the various stages along the continuum, it would follow that since a non-viable fœtus does not attract the status of a legal person, then an *in vitro* embryo also would not attract the legal status of personhood.[289]

However, some commentators have questioned whether it is appropriate to use the jurisprudence relating to the fœtus to draw analogies between the *in vitro* embryo and the fœtus.[290] In the foetal rights jurisprudence, the fœtus is inextricably linked to the mother in a circumstance where the interests of the fœtus and the mother are in conflict and a choice to favour the interests of either the mother or the fœtus must be made. This is not the case where an *in vitro* embryo is concerned because it exists as a separate entity from its progenitors, and consequently there is no imminent conflict of interest. Yet at the present time, an *in vitro* embryo cannot develop into a fœtus and thereafter into a human being without being implanted into a woman. Although a direct conflict of rights does not exist between the *in vitro* embryo and its progenitors at that point along the continuum of development, once it is transferred into a woman's body the rights of the woman are paramount in most jurisdictions and only as the embryo moves towards the other end of the continuum does the state's interest in the developing life become paramount.

Conclusion

It is apparent that the conception of life and the continuum of development play a large role in an individual's or society's view of the entities along that continuum. For example, sperm and eggs, which are at the beginning of the continuum, are openly bought and sold in the U.S., with very little opposition.[291] Whereas *in vitro* embryos are not openly sold in the U.S., even though there is no legislation prohibiting their sale.

Essentially, as the potential for life increases, the desire to protect the developing life also increases. Whether or not human rights instruments will play a role in protecting the potential for life that exists in an *in vitro* embryo is dependant on the legal status of *in vitro* embryo and the enactment of legislation to regulate activities associated with AHR generally, and *in vitro* embryos in particular. The question of the legal status of the *in vitro* embryo remains unanswered. However, at the present time, the most widely accepted approach is that *in vitro* embryos are *sui generis*. At this point in time, human rights would not apply to the *sui generis in vitro* embryo.

---

[287] For a summary of the jurisprudence respecting foetal rights see: J.E. Hanigsberg, "Power and Procreation: State Interference in Pregnancy" (1991) 23 Ottawa L. Rev. 36.

[288] Daar, *supra* note 205 at 635.

[289] Windsor, *supra* note 207 at 1009.

[290] Daar, *supra* note 205 at 635.

[291] Note that the AHR Act does not allow for the purchase or sale of gametes or *in vitro* embryos.

2.7 Further Issues to Consider

There is no question that AHR technology will continue to develop and improve. It is also likely that with the increased knowledge of the human genome and its impact on reproduction, along with the reality that infertility is on the rise globally, the number of individuals and couples who require AHR technology or desire to use AHR technology will increase. These future realities present a number of complex questions, including:

- Does a child have the right to have two biological parents of opposite sex?
- Does a child have the right to have a 'normal' or 'natural' genetic origin?
- What does the 'best interest of a child' mean in the context of AHR?
- Do parents have the right to have a child conceived using their own genetic material, even if this means using the genetic material from three biological parents?
- How far can the state regulate such activities?

These questions are multi-dimensional and require analysis from a legal, ethical and social perspective. From a human rights perspective, we must ask whether the current human rights framework adequately addresses the immediate and future issues that have arisen or may arise with respect to AHR.

2.8 Conclusion

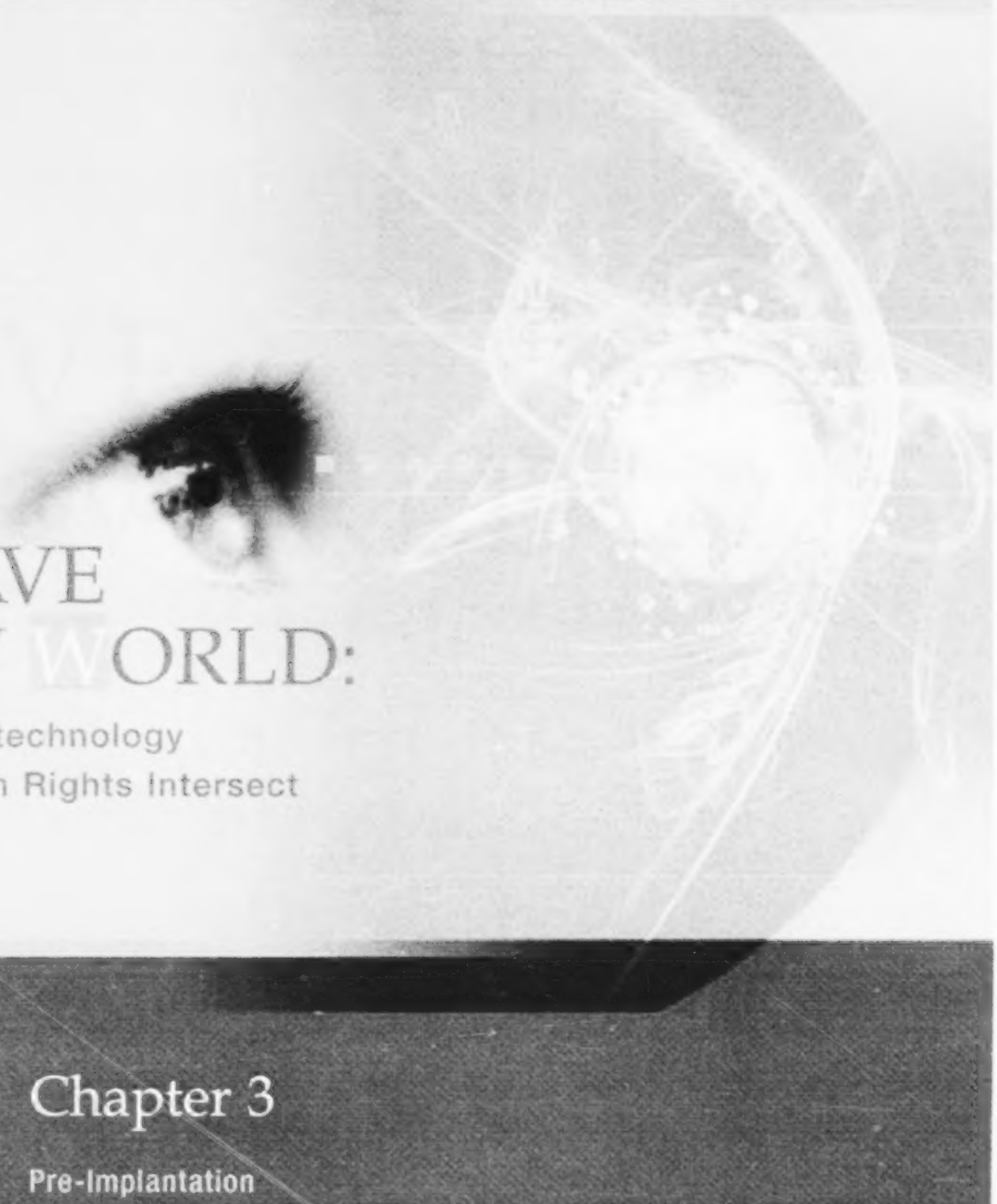
The *Charter* and Human rights legislation, such as the *Canadian Human Rights Act*, as well as the various provincial human rights statutes, are applicable to certain aspects of AHR, namely the equitable provision of services.

It is inevitable that disputes will arise with respect to AHR. In addition, the lack of jurisprudence applying human rights principles to AHR currently represents a gap in our understanding of what human rights may be engaged.

Another challenge, as the discussion in this chapter illustrates, is that many of the domestic and/or international human rights engaged in the context of AHR, such as the right to reproductive autonomy, the right to health and the right to benefit from scientific knowledge are not well developed. Moreover, the rights that exist at international law, but have no corresponding right in our domestic law, are difficult to enforce. Even the more developed rights, such as the right to equality or the right to security of the person have not yet or have rarely been applied in the context of AHR. This is not surprising, given that in general, the law lags behind the development of technology.

For the immediate future, it is apparent that the human rights issues related to AHR will require the application of traditional human rights concepts to very non-traditional problems or issues. However, other rights or concepts may emerge to assist in addressing the various issues that arise. For example, the emerging concept of human dignity will likely play a leading role in the future domestic and international discourse on this subject.

Government of Canada | Gouvernement du Canada



A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 3

Pre-Implantation Genetic Diagnosis

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 3

Table of Contents

3.1 Introduction 3–1

3.2 PGD 3–2

3.3 Background 3–3

3.4 Issues 3–5

3.5 Issue 1: The right to access PGD for medical reasons 3–5

- 3.5.1 International and Regional Instruments 3–5
- 3.5.2 The Law in Other Jurisdictions 3–7
- 3.5.3 Academic Literature and Commentary 3–12
- 3.5.4 The Law in Canada 3–13
- 3.5.5 Discussion 3–19

3.6 Issue 2: The right of parents to use PGD to select *in vitro* embryos based on certain favoured genetic traits 3–23

- 3.6.1 A Gene for Deafness 3–23
- 3.6.2 A Desired Sex 3–24
- 3.6.3 A Donor Child 3–26
- 3.6.4 Conclusion 3–27

3.7 Issue 3: The *In Vitro* Embryo 3–27

- 3.7.1 The Right to Life 3–27
- 3.7.2 The Right to Be Born With a Sound Mind and Body 3–28

3.8 Conclusion 3–39

Chapter 3

Pre-Implantation Genetic Diagnosis

Judy Hunter

3.1 Introduction

> *The temporal implications of genetic technology will require international human rights organizations to revisit issues surrounding the rights of the unborn that persist despite the abortion debate.*[1]

The ability of scientists to fertilize a human egg with sperm outside the body of a woman was hailed as a feat of technology that would enable the infertile to have children. Since the late 1970s, medical and scientific research in this area has focused on improvements in assisted human reproduction ("AHR") procedures and technologies. An example of a recent technological development in this area is pre-implantation genetic diagnosis ("PGD") which allows the detection of a genetic anomaly in the *in vitro* embryo. [2]

In 1989, the Government of Canada appointed the Royal Commission on New Reproductive Technologies ("Commission") to inquire into and report on the current and potential medical and scientific developments relating to new reproductive technologies. The Commission's mandate was very broad; it was asked to consider the social, ethical, health, research, legal and economic implications of such technologies.[3]

In 1993, the Commission issued its final report, entitled "Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies" ("Final Report").[4] With respect to PGD of the *in vitro* embryo,[5] the Commission concluded:

> Preimplantation diagnosis is an experimental form of prenatal diagnosis involving *in vitro* fertilization…the available data indicate that preimplantation diagnosis is a difficult, invasive, expensive, and inefficient technique with very limited indications.[6]

With respect to prenatal diagnosis, the Commission noted that during its Canada-wide consultations:

> … most people in Canada think that the choice of whether to have prenatal diagnosis when at risk for a serious disorder, and whether to have an abortion if a disorder is diagnosed, should be left to each woman or couple in accordance with their own values and circumstances.[7]

The public would likely express the same viewpoint if asked about a prospective parent's right to choose whether to conduct PGD of their *in vitro* embryos when at risk for a serious genetic disorder, and to select only disease-free *in vitro* embryos for reproductive purposes.

---

[1] Maha F. Munayyer "Genetic Testing and Germ-Line Manipulation: Constructing a New Language for International Human Rights" (1997) 12 Am. U.J. Int'l L. & Pol'y 687 at 10 (Lexis Nexis).

[2] An "*in vitro* embryo" is one that has been created and exists in a Petri dish, i.e., outside a woman's body. An "*in utero*" or "*in vivo* embryo" is one that has been conceived and exists within the woman's body.

[3] Royal Commission on New Reproductive Technologies. *Proceed With Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services, 1993) at 2.

[4] See Chapter 2 of the project paper for a more detailed discussion of the Royal Commission.

[5] "fœtus" is defined as the unborn human more than eight weeks after conception (Concise Oxford Dictionary, 10th Ed.). "Embryo" is defined as the unborn human in the first eight weeks following fertilization or conception (Concise Oxford Dictionary, 10th Ed.). "*In utero*" means within the mother's uterus or womb. "*In vitro*" refers to outside the human body and in a glass dish.

[6] *Supra* note 3 at 824.

[7] *Ibid.* at 788.

In Canada, access to PGD is currently controlled by the medical profession. The decision as to whether an individual or couple should undergo *in vitro* fertilization and PGD is a private one made by an individual or couple in consultation with their physician.

This chapter will identify and examine the human rights issues that arise with respect to PGD of an *in vitro* embryo. The chapter begins with a general discussion of PGD, a background section briefly explaining the science and technology, and a section identifying the relevant human rights issues. The rest of the chapter is organized under the following headings: (1) the relevant international law and principles, (2) the law in other jurisdictions, (3) the relevant Canadian law, (4) academic or other commentary, (5) discussion, and (6) conclusion.

3.2 PGD

In the late 1980s, PGD was developed and made available to prospective parents in the United Kingdom ("U.K.").[8] In April 1990, Handyside and Hannersmith Hospital reported the first established pregnancies from biopsied human pre-implantation embryos.[9]

PGD permits the detection of specific genetic disorders and the sex of the embryo (to avoid a sex-linked disease). It allows the selection of only those *in vitro* embryos that are free of a genetic predisposition to disease (or selection by sex for a sex-linked disease) for transfer into the woman. At present, tests are only available to detect single-gene disorders, such as cystic fibrosis. Although PGD can confirm the presence of a genetic anomaly, it cannot predict the extent to which the *in vitro* embryo, if transferred into the womb and born alive, would be affected as a child or adult.

This technology could be viewed as increasing reproductive choice for individuals who might otherwise forego parenthood because of their risk of passing on a genetic disease or disorder to their offspring.[10] Prior to the development of PGD, once the woman was pregnant and prenatal testing revealed that the *in utero* embryo or fœtus had a genetic disease or disorder, the choices available to the woman or couple were limited. The woman or couple could choose a "genetic abortion,"[11] which often resulted in physical and emotional trauma, as well as feelings of guilt for the parent,[12] or they could choose to complete the pregnancy with the possibility of raising a seriously ill or disabled child. PGD allows the embryo to be tested *in vitro*, and only those embryos that are believed to be free of a particular genetic disease are transferred to the womb in the hopes of a pregnancy.

Today, the number of world-wide centres offering PGD is on a steady increase.[13] In 2000, the European Society of Human Reproduction and Embryology ("ESHRE") PGD Consortium began collecting statistics from participating fertility centres around the world with respect to the use of PGD.[14] ESHRE's three published reports (1999, 2000 and 2001) reveal a steady increase in referrals for and use of PGD.[15]

---

[8] Anuja Dokras, M.D.Ph.D. (Department of Obstetrics and Gynaecology, Yale University School of Medicine, U.S.), Pre-Implantation Genetic Diagnosis, Vol. 1 No.5 at 1 (http://www.hygeia.org).

[9] A.H. Handyside et al., "Biopsy of Human Preimplantation Embryos and Sexing by DNA Amplification" (1998) February 18 Lancet 347-49; A.H. Handyside et al., "Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-Specific DNA Amplification" (1990) 344 Nature 768-70.

[10] Joint Canadian Fertility and Andrology Society/Society of Obstetricians and Gynaecologists of Canada, "Policy Statement: Ethical Issues In Assisted Reproduction" (1999) Journal SOGC 4 at 32.

[11] "Genetic abortion" is the term given in the literature for an abortion on the basis of medical information about the genetic status of the fœtus.

[12] Jason Christopher Roberts, "Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas" (2002) Duke L. & Tech. Rev. at 12.

[13] ESHRE, "Preimplantation Genetic Diagnosis Consortium: Data collection III" (May 2001) at 233.

[14] *Ibid.* (ESHRE); On February 16, 2004, Dr. Joyce Harper, Senior Lecturer in Human Genetics and Embryology at the UCL Centre for Preimplantation Genetic Diagnosis (London, England) announced that she has information that 86 centres worldwide are now conducting PGD (http://www.ucl.ac.uk).

[15] ESHRE, "Preimplantation Genetic Diagnosis Consortium: preliminary assessment of data from Jan. 1997 to Sept. 1998" (1999) 14 Human Reproduction no. 12, at 3138-3148; ESHRE, "Preimplantation Genetic Diagnosis Consortium: Data collection II" (May 2000), (2000) 15 Human Reproduction no. 12, at 2673-2683; ESHRE "Preimplantation Genetic Diagnosis: Data collection III" (May 2001), (2002) 17 Human Reproduction no. 1, at 233-246. NOTE: Canada is not contributing to this data collection since we only have one fertility centre performing PGD.

The increased use of PGD can be explained in part by the success of the Human Genome Project,[16] as well as improvements in the technology which have made PGD more reliable. In addition, individuals and couples in certain countries have started using PGD for non-medical reasons, such as selecting *in vitro* embryos on the basis of sex for social or cultural reasons.[17]

The most recent ESHRE report (2001) noted that PGD is now being used for selecting *in vitro* embryos that have the potential of becoming a donor child.[18] PGD allows for the selection of *in vitro* embryos that have the exact genetic traits needed to provide a cell transplant for an existing sibling with a genetic disease. Once the donor child is born, stem cells can be retrieved from his or her umbilical cord and placenta (tissues that would normally be discarded), and donated for transplant to the sibling.

3.3 Background

The Science

PGD of an *in vitro* embryo includes the use of several different technologies and processes.

First, an *in vitro* embryo must be created. The woman is given large doses of hormones to hyperstimulate her ovaries into producing a number of ova (eggs) in a single cycle, as opposed to the usual single egg in a typical cycle. Following hyperstimulation, as many eggs as possible are retrieved from the woman's ovary. These are either mixed with her partner's or a donor's sperm in a Petri dish or a single sperm is selected and injected into the egg, to create an *in vitro* embryo.[19]

Second, the resulting *in vitro* embryos are grown in the lab until they reach the eight-cell stage, approximately three days after fertilization. At that point, the *in vitro* embryo is biopsied by removing one or two blastomeres[20] (cells) for molecular analysis. Blastomeres are totipotent cells which are capable of developing into any cell type or into an embryo.[21] The biopsy is not believed to adversely affect the further development of the *in vitro* embryo, which continues in the lab while the biopsied blastomere cells undergo analysis.[22]

Third, to perform molecular analysis on the cell, the genetic information must be extracted from the nucleus of the isolated blastomeres. Two different types of genetic information can be obtained, i.e., chromosomal and gene. Chromosomal is the most common type of information obtained.

---

[16] The Human Genome Project is a global, collaborative, scientific effort consisting of a number of national and international programs that began in the mid-1980s with the objective of mapping and sequencing the entire human genome (Allyn L. Taylor, "Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health" (1999) 25 Am. J. L. and Med. 479 at 5 (Lexis Nexis)). The Project involves compiling information on genetic and physical features of the human genome, mapping the DNA sequences and understanding the interactions between human genes. The Project began officially in 1990 as an international research effort with the objective of discovering the estimated 60,000 to 100,000 human genes, and mapping the genes onto each chromosome. It will have a significant impact on the development of prenatal and preimplantation genetic testing. (Alastair T. Iles, "The Human Genome Project: A Challenge to the Human Rights Framework" (1996) 9 Harv. Hum. Rts. J. 27 at 2-3 (Lexis Nexis). The project is intended to provide researchers with the genetic information to locate the genes responsible for various genetic diseases and disorders. It is predicted that eventually the emphasis will shift from disease treatment to disease prevention. (Wendy E. Roop, "Not in My Womb: Compelled Prenatal Genetic Testing" (2000) 27 Hastings Const. L.Q. 397 at 2-3 (Lexis Nexis)). On June 26, 2000, a first draft of the human genome was presented at a White House ceremony. By that time over 7,000 genes had been traced to specific chromosomes. The project has increased scientific knowledge with respect to single gene mutations that cause disease (including late onset diseases) (Kay Chung, *Designer myths: the science, law and ethics of preimplantation genetic diagnosis* (London: Progress Educational Trust, 1999) at 11. In February 2001, two competing groups (one public and one private) published their more complete analyses of the human genome. Both papers indicate that the human species possesses 30,000 or so genes, not the 100,000 that many predicted (just 11,000 more than the laboratory roundworm (Gerard Magill, PhD "The Ethics Weave in Human Genomics, Embryonic Stem Cell Research, and Therapeutic Cloning: Promoting and Protecting Society's Interests" (2002) 65 Alb. L. Rev. 701 at 4 (Lexis Nexis); Southern California Center for Reproductive Medicine, "ART Preimplantation Genetic Diagnosis" November 2003 at 2 (http//www.socalfertility.com/art/PGD.shtm).

[17] A. Malpani and D Modi, "Preimplantation sex selection for family balancing in India" (Opinion: European Society of Human Reproduction and Embryology (ESHRE)) at 11.

[18] ESHRE, *supra* note 13 at 234. These children have been coined "saviour children" by the media in the UK because they have been selected from among a number of healthy *in vitro* embryos for reproductive purposes based on their potential ability to provide a cure for an existing sibling who is ill.

[19] For more details, see Chapter 2 of the project paper at 2 to 3.

[20] "Blastomeres" are totipotent cells which have the potential of giving rise to any cell type or to a human embryo (including all of its tissues and organs) and as well the fetal portion of the placenta (The President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) (http://www.bioethics.gov/reports/cloningreport/fullreport-print.html), The Concise Oxford Dictionary, 10th Ed.

[21] The President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) (http://www.bioethics.gov/reports/cloningreport/fullreport-print.html); The Concise Oxford Dictionary, 10th Ed.

[22] Dokras, *supra* note 8 at 1.

Chromosomal

The nucleus of each cell in the body, except for the sperm and ovum cells ("sex cells"), contains forty-six chromosomes. The nucleus of the sex cells contains twenty-three chromosomes. When the nucleus of a sperm and egg fuse during fertilization, the resulting embryo has forty-six chromosomes: half of the chromosomes come from each parent. Chromosomes are made up of as many as 30,000 genes,[23] which are specific stretches or regions of double-stranded deoxyribonucleic acid ("DNA").[24]

The most common use of PGD is to examine the genetic information at the chromosomal level. For example, some diseases and disorders are X-linked (such as haemophilia and Duchenne muscular dystrophy), which means that while the disease is carried by a healthy woman on the sex chromosomes, only her male children would be affected.[25] In the case of an X-linked disorder, instead of testing for mutations in the gene, the sex of the *in vitro* embryo is identified and only female embryos are transferred into the woman.[26]

The presence of additional, or the absence of certain, chromosomes can be indicative of a number of different diseases, such as Down's Syndrome, which results when the cell's nucleus has three copies of Chromosome 21 instead of two.[27] (This abnormality appears more frequently as the maternal age increases past 35 years.)[28]

Gene

The second and more complex use of PGD is to detect the presence or absence of a specific gene mutation in a chromosome within the cell's nucleus. The individual or couple who requires this type of information may be fertile but may carry a genetic mutation that could result in a particular disease or disorder in their offspring. These individuals undergo PGD to select for transfer (into the womb) only those *in vitro* embryos that do not have the particular gene mutation.[29]

The number of diseases known to be caused by a single gene mutation is growing as scientists learn more about the composition of the human genome.[30] To date, the most commonly tested single-gene disorders are cystic fibrosis, beta-thalassaemia and Huntington's disease. In addition, as knowledge of the human genome increases, tests for adult or late-onset diseases may be developed, such as those cancers with a genetic component.[31]

The director of the Human Genome Project, Francis Collins, predicted that by 2010, genetic tests will be available to diagnose diseases, to predict future risk for most of the common diseases, such as cancer, heart disease, mental disorders, and possibly to detect susceptibility to infections. In the future, it may be possible to screen for multifactorial diseases, such as asthma and the more complex cancers.[32]

It should be remembered, however, that genetic tests can currently only reveal whether an *in vitro* embryo is likely to have a genetic disease or disorder, but not the degree to which the condition will affect the future person.[33]

The use of PGD is not without controversy. In order to conduct PGD, an *in vitro* embryo must be created and manipulated. As noted earlier, the two blastomeres which are removed from the *in vitro* embryo for testing are totipotent, which means that they theoretically have the ability to develop into an embryo on their own if they were maintained under the proper conditions. Performing PGD on the blastomeres destroys them. For those individuals who consider the embryo to be human life, PGD would likely raise ethical and moral concerns.

---

[23] A gene is a section of a deoxyribonucleic acid molecule that codes for or directs the production of protein products used by the organism to build up and repair its various parts, catalyze metabolic processes, or even regulate the activity of other genes. The genes are arranged along rod like structures called chromosomes. (Anne Lawton, "The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning" (1998/99) 87 Ky. L.J. 277 at 3 (Lexis Nexis).

[24] Wendy E. Roop, "Not in my womb: Compelled Prenatal Genetic Testing" (2000) 27 Hastings Const. L.Q. 397 at 2-3 (Lexis Nexis).

[25] Kay Chung, *Designer myths: the science, law and ethics of preimplantation genetic diagnosis* (London: Progress Educational Trust, 1999) at 10 to 11.

[26] *Ibid.* at 11.

[27] Southern Calif Centre for Reproductive Medicine, "ART Preimplantation Genetic Diagnosis" (November 2002 at 2. Online: http://www.socalfertility.com/art/pgd.shtml

[28] Royal Commission, *supra* note 3 at 847.

[29] Peter Braude (B.Sc., M.A., Ph.D. (Clinical Director of the Guy's and St. Thomas' Centre for Preimplantation Genetic Diagnosis, U.K.), "An overview of preimplantation genetic diagnosis" (presented at the Preimplantation Genetic Diagnosis Study Day (October 17, 2001)) at 1.

[30] *Supra* note 27.

[31] Chung, *supra* note 25 at 11; Trudo Lemmens "Why Regulate New Genetics?" (Spring 2004, Innovate, 14-17).

[32] Denise Avard and Bartha Maria Knoppers, "Screening and Children Policy Issues for the New Millennium" (ISUMA, autumn 2001) at 47.

[33] Munayyer, *supra* note 1 at 3 (Lexis Nexis).

Furthermore, PGD allows for the selection of embryos that are believed to be free of genetic disease, or that have certain desirable genetic traits, for transfer into a woman while the remaining *in vitro* embryos are discarded. This use of PGD raises concerns among many individuals regarding the practice of eugenics.[34]

3.4 Issues

Three issues that arise with respect to the use of PGD have been selected for discussion in this chapter. The first two issues discussed are from the perspective of the would-be parents, while the third issue is discussed from the perspective of an *in vitro* embryo.

The first issue considers whether prospective parents, at risk of passing on a serious genetic disease to their offspring, have a right to access PGD to make a decision concerning reproduction. The second issue examines whether prospective parents have a right to use PGD to select, for reproduction, only those *in vitro* embryos that have certain preferred genetic traits, such as a certain sex or the gene for deafness. The final issue examines whether the *in vitro* embryo has a right to life and whether it has a fundamental right to be born as a child with a sound mind and body.

3.5 Issue 1: The right to access PGD for medical reasons

Although there is no specific right to access PGD or information respecting one's embryo or fœtus in international or regional human rights instruments, there are certain obligations imposed on State Parties in those instruments that suggest that women and perhaps couples have a right to reproductive freedom. Reproductive freedom could be viewed as containing two equal but opposite rights: the right to reproduce and the right not to reproduce. One could argue that information about the genetic status of one's *in vitro* embryos is essential for reproductive autonomy. Such information may be necessary for some persons to assist in their decision-making regarding reproduction. For example, if PGD revealed that one's *in vitro* embryos carried a genetic anomaly that would likely result in the child being born with a severely debilitating disease, one might choose not to reproduce.

3.5.1 International and Regional Instruments

As noted in Chapter 2, there is no specific reference to assisted human reproduction in international instruments. Neither is there a specific reference to PGD. There are, however, a number of international instruments that provide a right to "found a family."[35] This right is contained in the *International Covenant on Civil and Political Rights*[36] ("ICCPR") which Canada has ratified. The Human Rights Committee ("HR Committee"), which oversees the implementation by State Parties of the provisions of the ICCPR, provided its interpretation of the right to found a family in *General Comment 19*. The HR Committee noted that the right implies, in principle, the possibility to procreate and live together."[37]

Canada has ratified the *Convention on the Elimination of All Forms of Discrimination against Women*[38] ("CEDAW"). It obliges states to ensure that women have access to information and advice regarding "family planning" (Article 10(1)(h)).[39] Article 16(1)(e) obliges states to ensure that women have the right to decide freely the number and spacing of their children and ensure their access to the "information, education and means" to exercise these rights.[40] In 1993, the CEDAW Committee adopted the only authoritative interpretation of the right to family planning in *General Recommendation 21*.[41, 42]

---

[34] "Eugenics" may be defined as the science of controlled breeding to increase the occurrence of desirable heritable characteristics in a population (Concise Oxford Dictionary, 10th ed.).

[35] *Universal Declaration of Human Rights*, GA Res. 217 (III), UN GAOR, 3rd Sess., Supp. No. 13, UN Doc. A/810 (1948), article 16; *European Convention for the Protection of Human Rights and Fundamental Freedoms*, article 12; *International Covenant of Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171, entered into force 23 March 1976, article 23.

[36] *Ibid.*

[37] GC No. 19/38 on article 23 of the ICCPR, UN Doc. CCPR/21/rev.1/Add.2 at para. 5. See Chapter 2 for a more in-depth discussion.

[38] *Convention on the Elimination of all Forms of Discrimination against Women*, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46 (entered into force September 3, 1981).

[39] *Ibid.* — article 10(h):

> States Parties shall take all appropriate measures to eliminate discrimination against women in order to ensure to them equal rights with men in the field of education and in particular to ensure, on a basis of equality of men and women:
>
> (h) Access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning. [emphasis added]

[40] *Ibid.* — article 16(1)(e):

> 1. States Parties shall take all appropriate measures to eliminate discrimination against women in all matters relating to marriage and family relations and in particular shall ensure, on a basis of equality of men and women:
>
> (e) The same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights.

The CEDAW Committee noted that the responsibilities of bearing and raising children affect women's right to access education, among other things, and place an unequal burden of work on women. For these reasons, women are entitled to decide the number and spacing of their children.[43] Recommendation 21 stated that a woman's decision to have or not to have children should not be limited by a spouse, parent, partner or government. Women must have information about contraceptive measures and family planning services.[44]

The CEDAW Committee's interpretation, outlined in Recommendation 21, reinforces the view that women have a right to procreational autonomy. Some commentators argue that the right to found a family and the positive element of the right to family planning are related to an individual's or couple's right to have a child and thus implicitly guarantee a right to procreate or reproduce.[45]

At the international level, however, there are multiple interpretations of a right to procreate or reproduce.[46] There is uncertainty as to whether such a right would include a right to obtain information about the status of the fœtus or, in the case of AHR, the status of the *in vitro* embryo in order to decide whether to procreate.

The CEDAW states in article 5(a):

> Article 5 – States Parties shall take all appropriate measures:
>
> (a) To modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes or on stereotyped roles for men and women;

The CEDAW Committee has not issued recommendations regarding article 5 that would assist with its interpretation or to further inform States Parties of their obligations.

With respect to regional instruments, the Council of Europe's *Convention on Human Rights and Biomedicine*[47] ("*Convention*") provides the following in Articles 12 and 14:

> Article 12 – Predictive genetic tests
>
> Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed *only for health purposes* or for scientific research linked to health purposes, and subject to appropriate counselling. [emphasis added]
>
> Article 14 – Non-selection of sex
>
> The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

The Explanatory Report[48] to the *Convention* notes in paragraph 83 that "Article 12 as such does not imply any limitation of the right to carry out diagnostic interventions at the embryonic stage to find out whether an embryo carries hereditary traits that will lead to serious diseases in the future child."[49]

---

[41] *Convention on the Elimination of all Forms of Discrimination against Women*, Recommendation 21, Equality in marriage and family relations (Thirteenth session, 1992), Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, U.N. Doc. HRI\GEN\Rev. 1 at 90 (1994).

[42] Maja Kirilova Eriksson, *Reproductive Freedom: In the Context of International Human Rights and Humanitarian Law* (The Hague, The Netherlands: Kluwer Law International, 2000) at 185.

[43] Recommendation 21, *supra* note 39 at para. 21.

[44] *Ibid.* at para. 22.

[45] Eriksson, *supra* note 42 at 188; M. Tardu, "Relationships between human rights and population issues" (1990) Population and Human Rights UN New York at 55; Statens Medicinsk-etiska Rad, *Assisterad befruktning*, Stockholm 19 April 1995 at 15; J.A. Frowein & W. Peukert, *Europaische MenschenRechtsKonvention*, Kehl 1996 at 424.

[46] See Chapter 2 of the paper for a detailed discussion.

[47] *Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine* (Oviedo, 4.IV.1997) (Council of Europe, European Treaty Series, No. 164).

[48] *Explanatory Report to the Convention on Human Rights and Biomedicine* (Council of Europe, European Treaty Series, No. 164.) (http://conventions.coe.int/Treaty/en/Reports/Html/164.htm.) (hereinafter Exp Report).

[49] *Ibid.* (Exp Report) at para. 83, page 15.

With respect to Article 14, the Explanatory Report notes that "…it is not permissible to use a technique of medically-assisted [*sic*] procreation in order to choose a future child's sex, except where serious hereditary sex-related disease is to be avoided."[50] Paragraph 94 of the Explanatory Report notes, however, that it is up to the law of each country to determine what will be considered a "serious hereditary sex-related disease".[51]

In the spring of 1996, Canada was granted observer status on the Council. Although the *Convention* is open to signature by non-member states, Canada has not signed. Articles 12 and 14 of the *Convention* could, however, be introduced in a Canadian court as indicative of how European countries have dealt with these issues.

Conclusion

The provisions of the ICCPR and CEDAW could not form the basis of an action in a Canadian court, but they could be cited, along with the *Declaration*, to support a particular interpretation of the *Canadian Charter of Rights and Freedoms*[52] ("*Charter*") or of domestic legislation. The lack of jurisprudence at the international level regarding the right to found a family makes it difficult to predict how these provisions would be interpreted by a Canadian court.

3.5.2 The Law in Other Jurisdictions

The following will outline the law regarding the right to access PGD in the United States ("U.S."), Germany and the UK. These countries were chosen because they provide examples of three distinct state approaches to the practice of PGD.

The U.S.

In the U.S., there is no federal legislation respecting PGD. Fertility clinics are free to conduct PGD within the limits set by the laws of each state.[53] Only a handful of states explicitly address the use of PGD. Ten out of fifty states prohibit embryo research but six of those exempt PGD and thus allow it.[54] The other four states restrict the use of PGD to those situations where it can be shown to be beneficial, and without risk, to the *in vitro* embryo.[55]

It may be that the degree of control exercised by a state over the use of PGD correlates with the state's view of the moral and legal status of the *in vitro* embryo. This appears to be the case in Louisiana, which is one of the four states that prohibit PGD. It assigns rights to the *in vitro* embryo from the moment of conception. Under the Louisiana *Civil Code*, the *in vitro* embryo is protected and is deemed to be a juridical person who can sue and be sued, until such time as it is implanted in a woman's womb.[56] Louisiana prohibits PGD, unless it can be demonstrated that the procedure would benefit and be risk-free for the *in vitro* embryo. Both of these criteria would arguably be difficult to meet since PGD is never without risk to the *in vitro* embryo and, as a result of PGD, any *in vitro* embryos with a genetic anomaly would most likely be left to perish.

American jurisprudence has recognized that women have a constitutionally protected right to terminate a pregnancy up to the point of foetal viability, under the right to privacy and to liberty in the First, Fourth, Fifth and Fourteenth Amendments[57] to the *U.S. Constitution*. At the point of foetal viability, the state's interest in the developing fœtus may be such that the state can impose limitations on a woman's right to terminate the pregnancy.[58]

---

[50] *Ibid.* (Exp Report) at para. 93, page 16.

[51] *Ibid.* (Exp Report) at para. 94, page 16.

[52] *Constitution Act, 1982*, Schedule B, 1982, c.11, *Canadian Charter of Rights and Freedoms*, entered into force on April 17, 1982).

[53] Chung, *supra* note 25 at 15.

[54] Timothy Stoltzfus Jost, "Rights of Embryo and foetus in Private Law" (2002) 50 Am. J. Comp. L. 633 at 640; June Coleman, "Playing God or Playing Scientist" (1996) 27 Pac. L.J. 1331 at 1354 (The ten states are: Mass., Mich., N.H., N.M., N.D., R.I., LA., Minn., PA., and ME.) (Lexis Nexis).

[55] *Ibid.* (Coleman) at 11 (The four states that limit the conduct of PGD are: Louisiana, Minnesota, Maine, and Pennsylvania.) (Lexis Nexis).

[56] Jost, *supra* note 54 at 633; Louisiana Civil Code § 26 (1988).

[57] "Privacy": Although the *U.S. Constitution* does not specifically provide a right to privacy, the court has held that it originates in the First, Fourth and Fifth Amendments to the *Constitution* (Sklar A Sherwood "Don't Hate Me Because I'm Beautiful…And Intelligent…And Athletic: Constitutional Issues in Genetic Enhancement and the Appropriate Legal Analysis" (2001) 11 Health Matrix 633 at 5-6 (Lexis Nexis)). The courts have held that the rights secured by this guarantee to privacy are fundamental rights. For example, the right to procreate and the right not to procreate were both derived from the guarantee of privacy and thus they are considered fundamental. These rights are fundamental because they are located within areas of such a personal nature that unwarranted governmental intrusion is improper; these rights are not easily restricted by the state. Fundamental rights are granted the highest protection under the law. However, they are not limitless: the state can infringe on a fundamental right but only if it has a compelling reason and the infringement is accomplished through the least restrictive means.
"Liberty": The Fourteenth Amendment extends to the states the Fifth Amendment Due Process Clause's guarantee that "no person shall be deprived of life, liberty, or property without due process of law." The Due Process Clause of the *U.S. Constitution* includes a substantive component, which provides heightened protection against government interference with individual liberty interests under the First and Fourteenth Amendments. "Liberty denotes more than freedom from bodily restraint, but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home, and bring up children… and generally to enjoy these privileges long recognized… as essential to the orderly pursuit of happiness by free men [and women]." (Kelly M. Plummer "Ending Parents' Unlimited Power to Choose: Legislation is Necessary to Prohibit Parents' Selection of Their Children's Sex and Characteristics" (2003) 47 St. Louis L.J. 517 at 5 (Lexis Nexis).)

In the case of prospective parents who are at risk of passing on a serious genetic disorder or disease to their offspring, there would be an obligation on the attending physician to advise them of the risks and to recommend either PGD (if legal in the state) or prenatal genetic testing. The information from such testing might be viewed by the prospective parent as crucial to the making of an informed decision regarding reproduction. In those instances where the physician failed to inform the parent of the risk or failed to advise them regarding genetic testing and a seriously affected child was born, the parent might be in a position to sue the physician on the basis of negligence. In a majority of cases, these actions are in the nature of a tort framed as either "wrongful birth," when it is a court action taken by the parents, or "wrongful life," when it is a court action taken on behalf of the child.

The Supreme Court of California held in *Turpin v. Sortini*,[59] an action for wrongful life, that:

> ...in deciding whether or not to bear such a [disabled] child parents may properly, and undoubtedly do, take into account their own interests, parents also presumptively consider the interests of their future child. Thus, when a defendant negligently fails to diagnose a hereditary ailment, he harms the potential child as well as the parents by depriving the parents of information which may be necessary to determine whether it is in the child's own interest to be born with defects or not to be born at all.[60]

There has been some jurisprudence in those states that prohibit foetal experimentation where the courts have linked a constitutional right to information with reproductive freedom. In *Margaret s. v. Treen*[61] ("*Margaret s. II*"), there were multiple issues before the Court relating to provisions of a Louisiana state law regarding abortion. One issue was whether the legislative provision prohibiting *in utero* and *in vitro* foetal experimentation was constitutional. The plaintiffs alleged that the provision would have the effect of catching procedures involving the fœtus which might be considered "experimentation" but which would be therapeutic to a pregnant woman. In addition, the plaintiffs argued that the provision unconstitutionally burdened a doctor's right to conduct medical and scientific research.[62]

The U.S. District Court held that the prohibition respecting foetal experimentation, which carried substantial criminal penalties, unconstitutionally burdened a woman's right to an abortion and infringed on the rights of physicians to participate in foetal research.[63] In reaching these conclusions, the Court stated:

> The decision whether or not to beget or bear a child is at the very heart of this cluster of constitutionally protected choices recognized as the right of privacy...*The Court finds that this statute unduly limits the medical information obtainable through experimentation in that it deprived women of information concerning the likelihood of fetal deformity in their future pregnancies.* Such experimentation which might be therapeutic to the woman would be prohibited by [the statute] because it would not be therapeutic to the aborted, dead fetus. The right of women to make reproductive choices free of undue burdens imposed by the state is further violated by [the statute] in that the information needed to improve the accuracy and reliability

---

[58] *Roe v. Wade*, 410 U.S. 113 (1973).

[59] *Turpin v. Sortini et al.*, 31 Cal. 3d 220; 643 P.2d 954; 182 Cal. Rptr. 337; 1982 (Supreme Court of California) (Lexis Nexis).

[60] *Ibid.* at 10 (Lexis Nexis).

[61] *Margaret s. v. Treen*, 597 F. Supp 636, 673 (E.D. La. 1984) (District Court) (QL).

[62] *Ibid.* at 31 (QL).

[63] *Ibid.* at 33 (QL). The right of physicians to engage in their profession, although not recognized as a fundamental right, nonetheless is entitled under the Constitution to protection from arbitrary infringement. The court defined "liberty" to include "the right to engage in any of the common occupations of life." The court noted that "[a] state law will not be permitted to deny a person the right to pursue his occupation (including the physician class in this case) unless it is rationally related to the achievement of a legitimate state interest ...The state's interest in protecting fetal life does not continue past the death of the fetus ...There is no Louisiana law that prohibits experimentation on a deceased human being and, in fact, such experimentation is conducted during autopsies which are routinely performed ...Under [Louisiana] statute, a mother could donate the body of her child to medical science for [education, research or the advancement of science] ...purposes, but the criminal penalty imposed by [this statute] would effectively prohibit the donation of a mass of aborted tissue. This statute draws a distinction between a dead fetus and a deceased human being. There is no rational basis to draw such a distinction."

> of amniocentesis and other pre-natal diagnostic methods is dependent on the use of aborted fetal tissue for experimentation.[64] [emphasis added]

The District Court held that because fundamental rights encompass the entire process surrounding abortion, the prohibition on foetal experimentation, which could include diagnostic testing, violated the constitutionally protected right of women to make reproductive choices.[65] Presumably, the fundamental right to reproductive choice is not limited solely to a decision respecting abortion, but extends to encompass decisions respecting child bearing and contraception.[66]

The decision of the District Court was appealed to the Fifth Circuit Court,[67] which criticized the District Court for avoiding the real constitutional issue raised: whether a statutory ban on experimentation would inevitably limit the kinds of tests available to women and their physicians and thus could not help but infringe on a woman's fundamental rights.[68] The Fifth Circuit Court noted that every medical test that is now "standard" was once an "experiment." The Fifth Circuit Court, concurring with the District Court, held that the statute's prohibition on foetal experimentation was unconstitutionally vague.[69]

In *Jane L. v. Bangerter*[70] ("*Bangerter*"), the Tenth Circuit Court was asked to review a Utah statute that permitted discretionary experimentation aimed at acquiring genetic information about the embryo or fœtus. A lower court upheld the statute as constitutional by narrowly interpreting the term "experimentation" to mean "tests or medical techniques which are designed solely to increase a researcher's knowledge and are not intended to provide any therapeutic benefit to the mother or child."[71]

The Tenth Circuit Court disagreed, finding that the lower court had "blatantly" rewritten the statute in an attempt to provide clarity. The Court held that the word "benefit" was also ambiguous and pondered "if the mother gains knowledge from a procedure that would facilitate future pregnancies but inevitably terminate the current pregnancy, would the procedure be deemed beneficial to the mother?"[72] Since the statute was found not to provide clear boundaries to distinguish permissible acts from those that are criminal, the Court deemed it unconstitutional and invalid.[73]

In *Lifchez v. Hartigan*[74] ("*Lifchez*"), the District Court of Illinois considered the scope of the constitutionally protected right to procreational autonomy. The issue before the Court was whether s. 6(7) of the Illinois *Abortion Law*, which prohibited the sale of or "experiment" on a fœtus unless the experiment was "therapeutic" to the fœtus, offended due process principles in the Fourteenth Amendment of the *U.S. Constitution* by being so vague.

The Court found that the undefined terms "experiment" and "therapeutic" in the Illinois *Law* rendered it vague and thus violated the plaintiff's due process rights under the *Constitution*. The Illinois *Law* contained a provision purporting to exempt *in vitro* fertilization. However, the Court noted that, given the vague wording, PGD could be viewed as an experimental procedure that is not therapeutic to the *in vitro* embryo, and a procedure that could fall outside the *in vitro* fertilization exemption.[75]

In addition, the Court asked itself whether the Illinois *Law* impinged on a woman's right of privacy and reproductive freedom as established in *Roe v. Wade*.[76] The Court found that s. 6(7) was unconstitutional since it impermissibly restricted a woman's fundamental right of privacy; in particular, a woman's right to make reproductive choices free of government or state interference.[77]

---

[64] *Ibid.* at 32 (QL).

[65] *Ibid.*; Roberts, *supra* note 12 at 10 (Lexis Nexis).

[66] *Supra* note 61 at 1078-79.

[67] *Margaret s. v. Edwards*, 794 R.2d 994 (5th Cir. 1986) (Fifth Circuit Court).

[68] *Ibid.* at 999-1002.

[69] *Ibid.* at 999.

[70] *Jane L. v. Bangerter*, 61 F.3d 1493 (10th Cir. 1995).

[71] *Jane L. v. Bangerter*, 794 F. Supp. 1528 (D. Utah 1992).

[72] *Supra* note 70 at 1502.

[73] *Ibid.*

[74] *Lifchez v. Hartigan*, 1990 U.S. Dist. Lexis 4947 (United States District Court). (Lexis Nexis) Dr. Lifchez challenged the *Law* because he, along with other Illinois physicians, was concerned that the vague wording in its provisions, including s. 6(7), could be interpreted to apply to procedures, such as amniocentesis or chorionic villi sampling, undertaken to obtain information about the embryo or fœtus. If that was the case, physicians who performed such procedures could be charged under the statute's criminal sanctions.

[75] *Ibid.* at 6-7 (Lexis Nexis).

[76] *Roe*, *supra* note 58.

[77] *Lifchez*, *supra* note 74 at 15 (Lexis Nexis).

In support of its decision, the Court referred to the following passage from *Carey v. Population Services International*:[78]

> The decision whether or not to beget or bear a child is at the very heart of this *cluster of constitutionally protected choices*. That decision holds a particularly important place in the history of the right of privacy, a right first explicitly recognized in an opinion holding unconstitutional a statute prohibiting the use of contraceptives…and most prominently vindicated in recent years in the context of contraception…and abortion.[79] [emphasis added]

The Court held that s. 6(7) intruded on this "cluster of constitutionally protected choices" which included activities such as chorionic villi sampling (which provides information about the fœtus) and embryo transfer (an AHR procedure). The Court noted:

> Embryo transfer is a procedure designed to enable an infertile woman to bear her own child. It takes no great leap of logic to see that *within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than pregnancy.* Chorionic villi sampling is similarly protected. The cluster of constitutionally protected choices that includes the right to abort a fetus within the first trimester must also include *the right to submit to a procedure designed to give information about that fetus which can then lead to a decision to abort*. Since there is no compelling state interest sufficient to prevent a woman from terminating her pregnancy during the first trimester…there can be no such interest sufficient to intrude upon these other protected activities during the first trimester.[80] [emphasis added]

The Court concluded that s. 6(7) was unconstitutional "by encroaching upon this protected zone of privacy."[81] In *Lifchez*, the Court commented on AHR procedures, noting that the woman's decision to undergo a particular AHR procedure was a fundamental personal and private reproductive choice into which the state could not intrude. State intrusion or interference with a woman's access to such procedures, designed to provide information necessary for reproductive choice, would restrict her constitutionally protected right of privacy as articulated in the landmark Supreme Court decision of *Roe v. Wade* and *Carey v. Population Services International*.[82]

Summary

In both *Margaret S.* and *Lifchez*, the court dealt with rights related primarily to information about an *in utero* fœtus or embryo. The courts were concerned that overly broad statutory limitations on foetal experimentation might include foetal testing which could provide information necessary for the woman to make informed decisions about reproduction. In *Margaret S.*, the courts were willing to expand a woman's fundamental right to make reproductive decisions to include the right to information obtained from testing the *in utero* and *in vitro* fœtus. The courts were of the view that testing the dead fœtus could provide the necessary information to the woman to allow her to make future reproductive decisions. The Court in *Lifchez* held that the AHR procedure of embryo transfer, a process developed to allow an infertile woman to bear a genetically related child, falls within the "cluster of constitutionally protected choices" that are part of the fundamental right to procreative autonomy.

It may be that American courts would consider the information obtained from the testing of an *in vitro* embryo equally important for reproductive decision-making by women and would thus fall within a constitutionally protected sphere. At least one court has held that a decision to submit to an AHR procedure in order to procreate is similarly protected under the woman's right to procreational autonomy. It may be that both *in vitro* fertilization and PGD would be found by the courts to be fundamental choices that warrant constitutional protection.

Germany

In 1990, Germany passed the *Law for the protection of embryos*[83] ("*Embryo Protection Law*"). The *Embryo Protection Law* grants legal protection to life (including the *in vitro* embryo) before birth.[84] Some interpret the Law as conferring on an *in vitro* embryo human rights from the moment of fertilization.[85]

---

[78] *Carey v. Population Services International*, 431 U.S. 678, 52 L.Ed. 2d 675, 97 S.Ct. 2010 (1977).

[79] *Ibid.* at 685; *Lifchez, supra* note 74 at 15 (Lexis Nexis).

[80] *Lifchez, supra* note 74 at 16 (Lexis Nexis).

[81] *Ibid.* at 15-16 (Lexis Nexis).

[82] *Ibid.* at 15 (Lexis Nexis).

[83] *Law for the protection of embryos*, Bundesgesetzblatt, Part I, 19 December 1990, pp. 2746-2748).

The objective of the legislation is to preserve and protect *in vitro* embryos. The selection of an *in vitro* embryo on the basis of its sex, disability or tissue typing[86] would be prohibited under the Law. Under the legislation, the only activities permitted with respect to the *in vitro* embryo are those designed to benefit or to ensure its preservation. PGD is prohibited in Germany presumably because it involves the identification and selection of only those *in vitro* embryos that are "healthy," while discarding those that have a genetic anomaly.

Under section 3 of the *Embryo Protection Law*, the fertilization of an egg with sperm selected solely on the basis of their sex chromosome is prohibited. An exception is made, however, to permit sperm selection solely to avoid a serious sex-linked genetic disease.[87] Some pressure has been brought to bear on the government to permit PGD since the German position appears contradictory.

On the one hand, Germany allows prenatal testing of the fœtus. If the fœtus is found to have a particular genetic disease, the woman or couple are able to choose a genetic abortion without fear of prosecution by the state. Although abortion is illegal, the German Constitutional Court has specified that if a woman decides to have an abortion, she will not be prosecuted under the law as long as she visits a pregnancy counsellor prior to the abortion and she is less than fourteen weeks pregnant at the time of the abortion.[88]

And yet, on the other hand, the *Embryo Protection Law* prohibits the use of PGD which is conducted on the *in vitro* embryo prior to a pregnancy. PGD could eliminate the need for a genetic abortion by pre-selecting for transfer into the woman only those *in vitro* embryos that are free of a genetic predisposition to a particular disease.[89]

In Germany, there are individuals and groups, including women's groups that support the *Embryo Protection Law*, including the prohibition on PGD. These groups are concerned that widespread use of PGD to prevent disability and handicap would lead to negative attitudes in society towards those individuals who are chronically ill or disabled.[90] The German view is not surprising given the eugenics practiced by the Nazis in Germany before and during World War II.

The U.K.

PGD is a regulated activity under the U.K.'s 1990 *Human Fertilisation and Embryology Act*[91] ("*HFE Act*"). It is permitted when the individual or couple are at risk of passing on a genetic disease or when the woman is over the age of 35 years. Practitioners require a licence from the Human Fertilisation and Embryology Authority ("HFE Authority") to create an *in vitro* embryo, and further approvals to conduct PGD.

The *HFE Act* provides that a licence is required to undertake any "practices designed" to ensure that *in vitro* embryos are in a "suitable condition to be placed in a woman."[92] PGD has been determined to be such a practice and thus a clinic that wishes to undertake PGD must have a licence from the HFE Authority.

In addition to a licence, the clinic must apply to the HFE Authority for an approval to use PGD to diagnose or screen *in vitro* embryos for a particular genetic disease. Licences are not issued to undertake PGD on every genetic disease or disorder. Instead, a committee of the HFE Authority decides whether to issue an approval to undertake PGD testing for a particular disease or disorder on a case-by-case basis.

---

[84] Ecumenical Dialogue, *Biomedicin and Genetic Engineering* (1998) (http://www.ikd.de/dialogue/22396_3375.html).

[85] Chung, *supra* note 25 at 15.

[86] "Tissue typing" refers to a test to determine whether tissues are immunologically compatible with one another.

[87] *Supra* note 83.

[88] Eriksson, *supra* note 42 at 289; Questions and Answers about Germany: Health Care, Health Issues and Social Welfare. Online: http://www.germany-info.org/relaunch/info/facts/facts/questions_en/he.../healthissues3.htm

[89] Stephan Mueller, Ph.D. (Research Centre Biotechnology & Law, University of Lueneburg, Lueneburg, Germany), "Ethics and the regulation of Preimplantation diagnosis in Germany" (1997) 7 Eubios Journal of Asian and International Bioethics 5 at 5. Online: http://www.biol.tsukuba.ac.jp/~macer/EJ71D.html.

[90] Gabriele Pichlhofer and Sigrid Graumann, Frauen Forum Fotpflanzungsmedizin, Statement ReproKult, *The role of women in biomedical research*. Online: http://www.reprokult.de/posit_e.html.

[91] *Human Fertilisation and Embryology Act 1990* (c. 37). Online: http://www.legislation.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm.

[92] *Ibid.* at section 1 (Schedule 2).

Section 44 of the *HFE Act* extends section 1 of the *Congenital Disabilities (Civil Liability) Act 1976* to cover infertility treatments. This extension means that parents of children born disabled in the U.K. are permitted to sue physicians or clinics for their negligent performance of or their failure to undertake PGD on the *in vitro* embryo to detect a genetic disease.

Under the *HFE Act*, the use of PGD for the purpose of social sex selection is prohibited. In December 2003, the HFE Authority announced the results of public consultations regarding sex selection for social reasons. Approximately 80% of those who responded were in favour of retaining the legislative prohibition.[93]

The HFE Authority decided to issue licences allowing the use of *in vitro* fertilization, PGD and tissue typing to transfer only those *in vitro* embryos that are a genetic match for an existing sibling with a serious disease. The HFE Authority's decision was not without controversy and was challenged by Josephine Quintavalle, acting on behalf of a group whose purpose was to focus debate on ethical issues arising from AHR. One of the group's central tenets was absolute respect for the human embryo. Ms. Quintavalle sought judicial review of the HFE Authority's decision to licence tissue typing to select between healthy embryos.[94]

In *Quintavalle v. Human Fertilisation and Embryology Authority*[95] ("*Quintavalie*"), the High Court of Justice held that the phrase "practices designed to secure that embryos are in a suitable condition to be placed in a woman," in s. 1 (Schedule 2) of the *HFE Act*, permitted the HFE Authority to issue licences for PGD and tissue-typing. The Court held that PGD and tissue-typing were permitted under the *HFE Act* in order to secure an embryo, from among other healthy embryos, in a suitable condition for transfer, i.e., a tissue-type match for an already existing sibling who had a serious genetic disease.[96]

The Court, arguably, gave an expansive reading to the phrase "in a suitable condition" to allow PGD and tissue-typing. A narrow interpretation of the phrase might have restricted permissible practices to only those intended to ensure the health and safety of embryos.

In the U.K., clinics and practitioners must be licensed to perform PGD. To undertake tissue-typing to create an *in vitro* embryo that could become a tissue donor, an approval must be obtained from the HFE Authority. Approvals are granted only on a case-by-case basis.

3.5.2.1 Conclusion

It appears from a review of the laws in Germany, the U.S. and the U.K., that state legislation governing the practice of PGD closely mirrors the society's predominant view of the moral and legal status of the embryo. In those jurisdictions where the dominant view of the embryo is that of a developing human being or person, the state restricts testing and experimentation and/or assigns an embryo certain legal rights (Germany and Louisiana). In other jurisdictions, where the embryo is not considered a human being but may rather be viewed as *sui generis*, i.e., deserving of respect but not legal rights, the use of PGD is either unrestricted by the state or subject to state regulation, rather than state prohibition (the U.K. and the majority of states in the U.S.).

3.5.3 Academic Literature and Commentary

Despite the lack of jurisprudence with respect to PGD, there is no shortage of academic commentary on the subject, much of it from the U.S.

For many American academics, reproductive choice is viewed as part of the constitutionally protected right to procreational autonomy within the right to liberty. It is broad enough to encompass the right to choose to undergo an AHR procedure, as well as the right to choose to have the resulting *in vitro* embryos undergo PGD. Procreative autonomy is considered to include the choice to have healthy children, as well as the right not to have unhealthy children.[97]

---

[93] BioNews "HFEA rules out social sex selection" (November 12, 2003). Online: http://www.bionews.org.uk.

[94] *Quintavalle v. Human Fertilisation and Embryology Authority* [2003] E.W.J. No. 2533 (England and Wales Court of Appeal (Civil Division)) at 4 (QL). It is my understanding that *Quintavalle* is being appealed to the House of Lords.

[95] *Ibid.*

[96] *Ibid.* at 15.

Academics argue that procreative autonomy includes the right to obtain and use genetic information to make a reproductive choice. If individuals are free to decide whether to procreate, and if information as to the presence or absence of a genetic anomaly will affect that decision, it is obvious that prospective parents should be free to obtain and use the genetic information to assist in their decision-making.[98] These commentators are not suggesting that the right to obtain genetic information is a positive right or obligation on the state to provide genetic testing, but rather it is a negative right to access genetic testing free from government interference.[99]

Other commentators have argued that parents have a fundamental right, based in natural law, to make decisions respecting the care and upbringing of their children. With respect to genetic intervention, this fundamental right would enable parents to protect the health and bodily integrity of their children by making crucial decisions for their children at all stages of development.[100] Commentators suggest that this fundamental right would allow parents to make decisions, based on genetic information, to screen out disabling disease at the earliest stage of procreation, the embryonic stage. This right would allow parents to choose non-life, over disabled life, for their future child by choosing testing and by selecting for transfer only those *in vitro* embryos that are free of a genetic disease or disorder.[101]

There are, however, a number of academics who believe that the state must place some restrictions on the use of PGD, given the possible implications for society that may result from the unrestricted use of this technology. At least one commentator proposes a complete ban on PGD in the belief that it will lead to societal discrimination against persons born with disabilities.[102]

Commentators opposed to PGD often argue that the rejection of an embryo based on the possibility of disability is discriminatory, and that it is based on a misunderstanding of the nature of disability which devalues persons living with disabilities.[103] They further argue that if genetic diseases and disorders come to be viewed as avoidable, genetic testing, such as PGD and genetic therapy, would likely encourage narrow, socially determined standards of "health" and "normality" to prevail in society. These standards would reinforce existing prejudices against individuals with disabilities or physical characteristics that do not live up to a cultural ideal.[104]

Such standards could also generate social animosity toward parents who allow their children to be born "defective," despite knowledge of a potential genetic condition. As a result, the social focus might shift from encouraging tolerance of human diversity to developing methods to avoid or eradicate diversity.[105]

Furthermore, it is possible that PGD could be used to identify genetic traits beyond those that may cause severe genetic disorders or disease and thus transform PGD from a useful reproductive technique into a tool for eugenic purposes. By preventing the birth of at least some children with inherited disabilities, the use of PGD may reinforce discriminatory social attitudes towards disabled people in general.[106]

3.5.4 The Law in Canada

In Canada, a physician would likely recommend PGD where there is evidence that the individual or couple are at risk of passing on a severe genetic disease to their offspring, or when the maternal age is greater than

---

[97] John Robertson, "Genetic Selection of Offspring Characteristics" (1996) 76 B.U.L. Rev. 421 at 1.

[98] *Ibid.* at 2.

[99] Megan A. Jellinek, "Disease Prevention and the Genetic Revolution: Defining a Parental Right to Protect the Bodily Integrity of Future Children" (2000) 27 Hastings Const. L.Q. 369 at 16 (Lexis Nexis).

[100] *Ibid.* (Jellinek) at 4 (Lexis Nexis); Rebecca Knox, "Preimplantation Genetic Diagnosis: Disease Control or Child Objectification?" (2003) 22 St. Louis U. Pub. L Rev. 435 at 3-7 (Lexis Nexis).

[101] *Ibid.* (Jellinek).

[102] Jodi Danis, "Sexism and 'The Superfluous Female': Arguments for Regulating Pre-Implantation Sex Selection" (1995) 18 Harv. Women's L.J. 219 at 3 (Lexis Nexis).

[103] Jost, *supra* note 54 at 641; Robertson, *supra* note 97.

[104] Danis, *supra* note 102.

[105] Munayyer, *supra* note 1 at 4 (Lexis Nexis).

[106] Joint Canadian Fertility and Andrology Society/Society of Obstetricians and Gynaecologists of Canada, *Policy Statement: Ethical Issues in Assisted Reproduction* (1999) Journal SOGC 4 at 33-34.

35 years.[107] At the present time, Canada has only one centre providing PGD which is located in Montreal, Quebec.

The *AHR Act*

On April 22, 2004, certain portions of the federal *Act Respecting Assisted Human Reproduction and Related Research*[108] ("AHR Act") were proclaimed in force. Under the AHR Act, some uses of PGD are prohibited while others will be regulated as controlled activities. The Act permits the use of PGD for selecting only those *in vitro* embryos of a particular sex for medical reasons, i.e., to prevent, diagnose or treat a sex-linked disease or disorder. However, the Act prohibits the use of PGD, as well as other technologies, to identify the sex of *in vitro* embryos in order to select, for social or cultural reasons, only those of a certain sex for reproductive purposes (s. 5(1)(e) of the AHR Act). A person who contravenes this prohibition, depending on the type of offence, could be liable to a substantial fine and/or imprisonment.

The offence provisions in the AHR Act are based on the federal criminal law head of power in s. 91(27) of the *Constitution Act, 1867*. Section 60 of the Act provides that a person convicted of committing a prohibited act would, depending on the type of offence, be liable to a maximum fine of $250,000 to $500,000 and /or a maximum jail term of 4 to 10 years. A person who is convicted of contravening any of the regulations made under the Act would, depending on the type of offence, be liable to a maximum fine of $100,000 to $250,000 and/or a maximum jail term of 2 to 5 years (section 61).

The AHR Act provides the Governor in Council with an extensive regulation-making authority, as well as the authority to create the future Assisted Human Reproduction Agency of Canada ("Agency"). The use of PGD, for reasons other than social sex selection, will most likely be the subject of regulations under the Act, and physicians and/or clinics will most likely be required to obtain a licence from the Agency to conduct PGD. Furthermore, the Agency, once created would have authority to attach conditions to each licence, further controlling the practice of PGD.

The *Charter*

In order to invoke the application of the *Charter*, there must be a government action that arguably deprives a person of one of the protected rights or freedoms. Section 7 provides the interests and rights that would most likely be implicated in a situation where state action prevented a woman from accessing information about her *in vitro* embryo that would be necessary for her to make a reproductive decision.

The section 7 analysis undertaken by the courts could be viewed as a three-step process. First, the courts look to see whether there has been a state deprivation of one of the rights in section 7, i.e., life, liberty or security of the person. Second, the courts identify and define the relevant principle of fundamental justice. Third, the courts determine whether the state deprivation was in accordance with the principles of fundamental justice and if it was, then the state action would be found constitutional. If the deprivation was not in accordance with the principles of fundamental justice, then it would be either be found unconstitutional or the court would determine whether the state could justify the deprivation under section 1 of the *Charter*.

Case law

In Canada, the courts have recognized a woman's right to reproductive autonomy. This right, like all other rights, is not absolute. It can be limited by the state through legislation or regulations. Any state limitation would have to accord with the principles of fundamental justice and be justifiable. The following Supreme Court cases discuss reproductive autonomy.

---

[107] Canadian physicians currently look to either the Joint Policy Statement of the Canadian Fertility and Andrology Society and the Society of Gynaecologists of Canada ("Canadian Policy Statement") (Joint Canadian Fertility and Andrology Society/Society of Obstetricians and Gynaecologists of Canada, *Policy Statement: Ethical Issues In Assisted Reproduction* (1999) Journal SOGC 4 at 32.) or to the professional guidelines established by the Ethics Committee of the U.S. American Society of Reproductive Medicine ("U.S. Guidelines") (Ethics Committee of the American Society of Reproductive Medicine, *Sex selection and Preimplantation genetic diagnosis* (1999) 72 (No. 4) Fertility and Sterility 595.) for guidance with respect to providing PGD services.

[108] The *Act Respecting Assisted Human Reproduction and Related Research*, Third Session, Thirty-seventh Parliament, 52-53 Elizabeth II, 2004 (passed 12 March 2004 and certain sections proclaimed in force on 22 April 2004). Online: http://www.parl.gc.ca

In *R. v. Morgentaler*[109] ("*Morgentaler*"), a majority of the Supreme Court struck down the impugned provisions of the federal *Criminal Code* dealing with abortion, on the basis that the provisions restricted a woman's access to a therapeutic abortion and thus violated her section 7 *Charter* right to security of the person. The majority held that the *Criminal Code* provisions could not be justified by the government under section 1 of the *Charter*.

Section 7 of the *Charter* provides:

> Everyone has the right to life, liberty and security of the person and the right not be deprived thereof except in accordance with the principles of fundamental justice.

Section 1 of the *Charter* states:

> The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

In *Morgentaler*, there were three majority opinions and one dissenting opinion from the Court. Justice Wilson, writing one of the majority opinions for herself alone, based her reasons for decision on the section 7 *Charter* right to liberty and to security of the person. In her view, the liberty interest protected by section 7 is concerned not only with physical liberty but also with the fundamental concepts of human dignity, individual autonomy and privacy.

Wilson J. stated "[A]n aspect of the respect for human dignity on which the *Charter* is founded is the right to make fundamental personal decisions without interference from the state. This right is a critical component of the right to liberty."[110] In her view, section 7 grants women a degree of autonomy such that in the early stages of pregnancy, the woman has an unrestricted right to make personal decisions regarding her pregnancy free from state interference.[111]

Both Justice Beetz, writing one of the majority opinions on behalf of himself and Justice Estey, and Justice Wilson suggested, in *obiter*, that the state's interest in a developing human life could become compelling when the fœtus reached the point of viability, i.e., the point at which the fœtus could survive outside the mother's womb without artificial aid. They both noted that foetal viability might be a basis on which the state could draft valid legislative limits on a woman's right to an abortion.

Justice Wilson expanded on the suggestion as follows:

> It would be my view and I think it is consistent with the position taken by the United States Supreme Court in Roe v. Wade, that the value to be placed on the fœtus as potential life is directly related to the stage of its development during gestation. The undeveloped fœtus starts out as a newly fertilized ovum; the fully developed fœtus emerges ultimately as an infant...in balancing the state's interests in the protection of the fœtus as potential life under s. 1 of the Charter against the right of the pregnant woman under s. 7 greater weight should be given to the state's interest in the later stages of pregnancy than in the earlier.
>
> [...]
>
> A developmental view of the fœtus...supports a permissive approach to abortion in the early stages of pregnancy and a restrictive approach in the later stages. *In the early stages the woman's autonomy would be absolute: her decision, reached in consultation with her physician, not to carry the fœtus to term would be conclusive. The state would have no business inquiring into her reasons.* Her reasons for having an abortion would, however, be the proper subject of inquiry at the later stages of her pregnancy when the state's compelling interest in the protection of the fœtus would justify it in prescribing conditions...It seems to be, however, that it might fall somewhere in the second trimester.[112] [emphasis added]

---

[109] *R. v. Morgentaler*, [1988] 1 S.C.R. 30. It is important to note, however, that the Supreme Court left open the possibility that the government could impose restrictions on abortion after the foetus reached the point of viability outside the womb.

[110] *Ibid.* at 166.

[111] *Ibid.* at para. 260.

[112] *Ibid.* at para. 259 and 260.

In Justice Wilson's view, the state interest in the fœtus would only become compelling in the later stages of a pregnancy, sometime in the second trimester, and would be based on foetal viability. However, she found that the woman's autonomy would be absolute during the early stages of a pregnancy, when the developing fœtus exists as a newly fertilized ovum (an embryo).

Since *Morgentaler*, women in Canada have had the ability to terminate a pregnancy without fear of criminal sanction. This right would arguably apply whether the woman conceived through sexual reproduction or through an AHR procedure.

Although it did not raise any *Charter* arguments, the case of *Winnipeg Child and Family Services (Northwest Area) v. G.(D.F.)*[113] ("*Winnipeg*") provides comments from the Supreme Court regarding the *Charter*-protected liberty interest in section 7. In *Winnipeg*, the Court was asked whether it could exercise its *parens patriae* jurisdiction to protect an unborn child by ordering the mother into custody because of her glue-sniffing addiction. A majority of the Supreme Court held that the court does not have *parens patriae* jurisdiction over an unborn child and thus cannot make a custody order for the mother for the purpose of preventing harm to the unborn child.[114]

The majority decision was delivered by Justice McLachlin. In her reasons, she canvassed the law of tort and the scope of the court's *parens patriae* jurisdiction. Justice McLachlin noted that extending the *parens patriae* jurisdiction to the unborn would affect a broad range of liberty interests. It would allow the courts to make fundamental decisions for the pregnant woman, such as where to live and what medical treatment to undergo. She noted that the court's *parens patriae* jurisdiction has never been invoked as a basis for making such decisions on behalf of competent women, whether they are pregnant or not. In the majority's view, the extension of power sought in this case would have the effect of seriously intruding on the rights of women.[115]

Recent jurisprudence from the Supreme Court has since expanded and clarified to some extent the liberty interest in section 7. In *Godbout v. Longueuil (City)*,[116] ("*Godbout*") the Supreme Court was asked whether a municipal by-law restricting where an employee of the municipality could reside infringed the right to liberty under section 7 of the *Charter*. La Forest J. reiterated Justice Wilson's comments in *Morgentaler, supra*, regarding the section 7 liberty interest. He stated that in his view, the liberty interest in section 7 grants the individual a degree of autonomy in making decisions of fundamental personal importance.[117]

He emphasized that section 7 protects:

> …the right to an irreducible sphere of personal autonomy wherein individuals may make inherently personal choices free from state interference…this sphere of autonomy…[is not] so wide as to encompass any and all decisions that individuals might make in conducting their affairs…individuals cannot, in any organized society, be guaranteed an unbridled freedom to do whatever they please…the autonomy protected by the s. 7 right encompasses only those matters that can properly be characterized as fundamentally or inherently personal such that, by their very nature, they implicate basic choice going to the core of what it means to enjoy individual dignity and independence.[118]

The following cases illustrate that the *Charter* rights in section 7 can now be invoked outside the penal context in those situations where government action engages the justice system and its administration. In addition, the cases provide further insight into the scope of liberty under section 7 and into the scope of the section 7 right to security of the person.

In *New Brunswick (Minister of Health and Community Services) v. G.(J.)*[119] ("*G(J)*"), Chief Justice Lamer, writing for a majority of the Supreme Court, expanded the application of section 7 from the penal context to situations where state action engaged the justice system and the administration of justice. In *G(J)*, section 7 was held to apply in the context of a child protection/custody hearing. The Supreme Court was asked whether a parent has a constitutional right to state-funded counsel when the government sought an order to suspend a parent's custody of their child.

---

[113] *Winnipeg Child and Family Services (Northwest Area) v. G.(D.F.)*, [1997] S.C.J. No. 96 (File No.: 25508) (QL). (A judge of the superior court held that the court could exercise its *parens patriae* jurisdiction over the unborn and ordered the mother into custody. The Court of Appeal held that the existing law of tort and *parens patriae* could not support such an order and overturned the decision of the superior court judge.)

[114] *Ibid.* at 2.

[115] *Ibid.* at para.56.

[116] *Godbout v. Longueuil (City)*, [1997] 3 S.C.R. 844.

[117] *Ibid.* at para. 65.

[118] *Ibid.* at para. 66.

[119] *New Brunswick (Minister of Health and Community Services) v. G.(J.)*, [1999] 3 S.C.R. 46.

The majority held that not all state interference with the parent-child relationship would constitute an infringement of a parent's *Charter* right to security of the person. Rather, only those state actions that cause a "serious and profound effect on a person's psychological integrity" would qualify as a deprivation. The resulting psychological stress suffered by the parent must be more than "ordinary stress or anxiety."[120]

In finding that the government's act of removing the appellant's children violated her security of the person interest under section 7 of the *Charter*, the majority considered whether the state restriction was in accordance with the principles of fundamental justice.[121] The majority noted that the principles of fundamental justice respecting child protection hearings are both substantive and procedural. The custody hearing, while administrative rather than criminal in nature, remains adversarial. Without counsel, the appellant could not effectively participate in the hearing.[122] The majority concluded that the potential restriction of the appellant's section 7 rights would not have been in accordance with the principles of fundamental justice if the appellant had not been represented by state-funded counsel and the infringement would not have been saved by section 1 of the *Charter*.[123]

In *Gosselin v. Quebec*[124] ("*Gosselin*"), the Supreme Court restricted the application of section 7 to those situations where state action engaged the administration of justice. In *Gosselin*, the Court was asked whether the section 7 *Charter* right to security of the person includes the right to receive a particular level of social assistance from the state.[125] McLachlin C.J., writing for the majority, noted that "the dominant strand of jurisprudence on section 7 sees its purpose as guarding against certain kinds of deprivation of life, liberty and security of the person, namely, those that occur as a result of an individual's interaction with the justice system and its administration."[126]

The Chief Justice stated that section 7 does not protect against all activities that might infringe on life, liberty and security of the person. Rather, it only protects against those activities that can be attributed to state action implicating the justice system or the administration of justice. The administration of justice does not refer solely to processes operating in the criminal law. It can be implicated in a variety of circumstances, such as human rights processes, parental rights in relation to state-imposed medical treatment, parental rights in custody proceedings, and liberty to refuse state-imposed addiction treatment.[127] McLachlin C.J. noted that, to date, section 7 has been implicated in those situations where the state has deprived people of the right to life, liberty and security of the person. She stated that, in the future, section 7 may be interpreted to impose positive obligations on the state. However, since the case at bar did not involve a state action resulting in a section 7 deprivation, the majority held that the plaintiff's action failed.[128]

In *R. v. Malmo-Levine; R. v. Caine*,[129] the Supreme Court was asked, among other questions, whether the laws respecting the possession and trafficking of marihuana under the federal *Narcotic Control Act* violated section 7 of the *Charter*. One of the appellants alleged that the legislative provisions infringed his personal liberty under section 7. The other appellant alleged that the potential imprisonment for conviction of possession was not in accordance with the principles of fundamental justice.[130]

A majority of the Court held that the availability of imprisonment for the offence of simple possession was sufficient to trigger scrutiny under section 7. The majority noted that the *Charter* cannot be stretched to protect every activity a person defines as central to their lifestyle. Rather than protecting these types of lifestyle choices, the *Charter* serves to protect those basic choices that go to the core of what it means to enjoy individual dignity and independence.[131]

---

[120] Chapter 2 of the project paper at 30.
[121] *G(J)*, *supra* note 119 at 18.
[122] *Ibid.* at 21.
[123] *Ibid.* at 23.
[124] *Gosselin v. Quebec*, [2002] 4 S.C.R. 429. Online : http://www.lexum.umontreal.ca
[125] *Ibid.* at 28.
[126] *Ibid.* at 28.
[127] *Ibid.* at 29.
[128] *Ibid.* 29-30.
[129] *R. v. Malmo-Levine, R. v. Caine*, [2003] SCC 74. Online : http://www.lexum.umontreal.ca
[130] *Ibid.* at para. 81 and 82.

The majority held that the risk of jail is another matter; such a risk engages the appellants' liberty interest.[132] In this case, is the risk of a deprivation of liberty in accordance with the principles of fundamental justice?

The appellants agreed that the state may act to prohibit harm to others without violating the principles of fundamental justice. However, they argued that because marihuana is not harmful, it serves no state interest in depriving them of their liberty to possess marihuana and consequently the infringement of their liberty interest is not in accordance with the principles of fundamental justice.[133]

The Court rejected the appellants' argument that the principle of fundamental issue in the case was the "harm principle." Instead, the Court held that the valid state interest in this case was one of "avoidance of harm."[134] The law will not be found to be arbitrary or irrational when the state determines that the harm to be prevented is not *de minimis* or insignificant and the law is not grossly disproportionate to the state interest.[135]

A decision whether to reproduce or not would most likely be found by the courts to constitute a decision of fundamental personal importance and thus would qualify for *Charter* protection under section 7. The courts would most likely find that a choice to reproduce sexually or to reproduce through assisted reproduction technology falls within the *Charter*-protected sphere of personal decision making. The courts might adopt the American approach which broadened the scope of reproductive autonomy to include a right to access medical information about the *concepti* that was considered necessary for reproductive decision making. On the other hand, the courts in Canada might adopt a narrow approach and limit *Charter* protection only to the decision to reproduce or not to reproduce. This seems unlikely since it could be argued that information about the fœtus in the mother's womb is often necessary to allow women to make a reproductive choice, and thus it follows that information about the status of the *in vitro* embryo is equally important to allow women autonomous decision making. In fact, there may be compelling arguments that information regarding the genetic status of an *in vitro* embryo is more important to the woman since it allows her to make a reproductive decision prior to becoming pregnant and thus may avoid the physical and psychological risks that accompany abortion.

The following cases are important with respect to a discussion of one's right to access a particular medical therapy or treatment. In *Rodriguez v. British Columbia (Attorney General)*[136] ("*Rodriguez*"), the Supreme Court was asked whether section 241(b) of the *Criminal Code* infringed the appellant's section 7 *Charter* rights to life, liberty and security of the person by making it a criminal offence for another person to assist Ms. Rodriguez to commit suicide. The appellant was suffering from amytrophic lateral sclerosis, a terminal disease that would eventually cause her to lose the ability to speak, swallow, walk and move without assistance.[137]

Once she could no longer enjoy life, she wanted a physician to set up the technological means whereby she could end her life at the time of her choosing, and the physician providing assistance would not be subject to a criminal prosecution.[138] The majority reviewed other relevant cases starting with *Morgentaler, supra*, and concluded that security of the person encompasses: (1) personal autonomy, i.e., the right to make choices concerning one's own body, (2) control over one's physical and psychological integrity, and (3) basic human dignity, free from state interference in the form of criminal prohibitions.[139]

---

[131] *Ibid.* at para. 86.
[132] *Ibid.* at para. 89.
[133] *Ibid.* at para. 90 to 92.
[134] *Ibid.* at para. 130.
[135] *Ibid.* at para. 133 to 135.
[136] *Rodriguez v. British Columbia (A.G.)*, [1993] 3 S.C.R. 519.
[137] *Ibid.* at 520.
[138] *Ibid.*
[139] *Ibid.* at 588.

The Court noted that, in *Morgentaler, supra,* security of the person was found to include a right of access to beneficial medical treatment for a condition representing a danger to life or health without fear of criminal sanction.[140] A five-person majority of the Supreme Court held that although the prohibition infringed her rights to security of the person and liberty, it did not do so in a manner contrary to the principles of fundamental justice. Thus, the *Criminal Code* prohibition on assisted suicide was found to be constitutional.[141]

In *R. v. Parker*[142] ("*Parker*"), the Ontario Court of Appeal was asked whether prohibitions under two federal statutes regarding the cultivation and possession of marihuana violated the respondent's section 7 *Charter* rights to security of the person and liberty.[143] Parker alleged that the prohibitions interfered with his health and therefore his security of the person and liberty interests.

The Court of Appeal noted that *Morgentaler, supra,* is the leading case where medical treatment and the criminal law intersect. In that case, state interference with bodily integrity and state-imposed psychological stress, at least in the criminal law context, constituted a breach of security of the person. This view of the right to security of the person was adopted in *Rodriguez, supra,* and *G(J), supra.*[144]

The Court of Appeal relying on the Supreme Court's comments in *Morgentaler* and *Rodriguez* held that:

> ...deprivation by means of a criminal sanction of access to medication reasonably required for the treatment of a medical condition that threatens the life or health constitutes a deprivation of security of the person ... Depriving a patient of medication in such circumstances, through a criminal sanction, also constitutes a serious interference with both physical and psychological integrity.[145]

And later in the decision:

> ...the constitutional right to security of the person must include some protection from state interference when a person's life or health is in danger... There must be state intervention for "security of the person" in s. 7 to be violated. If a rule of criminal law precludes a person from obtaining appropriate medical treatment when his or her life or health is in danger, then the state has intervened and this intervention constitutes a violation of that man's or woman's security of the person. *Security of the person must include a right of access to medical treatment for a condition representing a danger to life or health without fear of criminal sanction.* If an Act of Parliament forces a person whose life or health is in danger to choose between, on the one hand, the commission of a crime to obtain effective and timely medical treatment and, on the other hand, inadequate treatment or no treatment at all, the right to security of the person has been violated.[146] [emphasis added]

3.5.4.1 Conclusion

The cases above illustrate that the courts consider some individual decisions or choices to be so fundamentally personal that they fall within a protected sphere. Not every choice will qualify for protection; the choice must relate to a matter that by its very nature goes to the core of what it means to enjoy independence and dignity.

3.5.5 Discussion

There is no jurisprudence in Canada dealing with whether a woman has a right to information about the medical or genetic status of her unborn child, let alone her *in vitro* embryo.

International Arena

As noted earlier, certain international human rights instruments contain articles that address family formation and planning and have been interpreted as providing women with reproductive autonomy. One commentator has suggested that an international right to reproductive autonomy can be found "using traditional human rights analysis, drawing upon existing international treaties and charters."[147] In her view, support for a human right to reproductive freedom can be found in three basic principles of international law: privacy, equality and health.[148]

---

[140] *Ibid* at 587.

[141] *Ibid* at 583.

[142] *R. v. Parker* (July 31, 2000). Online: http://www.canlii.org/on/cas/onca/2000/2000onca359.html.

[143] At trial, the judge held that the prohibitions violated the respondent's *Charter* rights under s. 7 to life, liberty and security of the person and were contrary to the principles of fundamental justice. Instead of striking down the prohibition, the trial judge read in an exemption for persons cultivating or possessing marihuana for their personal medically-approved use.

[144] *Ibid* at 18.

[145] *Ibid* at 20.

[146] *Ibid* at 22.

It is important to note that the CEDAW does not limit reproductive autonomy to the right to terminate a pregnancy. Rather, it could be interpreted as providing a broad right that includes rights relating to family planning, such as the right to decide the number and spacing of one's children. These rights appear to exist independently of a pregnancy. One could argue that the international right to reproductive autonomy, inferred from these instruments, encompasses and protects all decision making related to reproduction, such as decisions respecting genetic testing.

The international instruments and commentary could be used to inform the court's interpretation of the scope of reproductive autonomy under the liberty interest in section 7 of the *Charter* and any domestic legislation.

The courts could also be referred to the Council of Europe's *Convention* as an example of how other countries have dealt with PGD and genetic information. The *Convention* provides that genetic testing may be undertaken to determine the presence of a gene responsible for disease (article 12). The accompanying Explanatory Report notes that article 12 in no way limits diagnostic testing of the embryo to determine the presence of a gene that could lead to a serious disease in the future child.

Other Jurisdictions

The courts have been known to turn to American constitutional jurisprudence to inform its interpretation of the human rights and freedoms under the *Charter*. Some U.S. state courts have broadened the constitutionally protected right to procreational autonomy to include a right to access information that would assist a woman in making a decision regarding reproduction. Furthermore, at least one state court has held that the constitutionally protected right to procreational autonomy includes the right to choose to submit to an AHR procedure to become pregnant.

The Charter

The section 7 *Charter* right to liberty could be viewed as one of the basis for reproductive autonomy in Canada. One could argue that at the very least reproductive autonomy is comprised of two equal but opposite rights: the right to reproduce and the right not to reproduce.

Justice Wilson was of the view that the liberty interest in section 7 was concerned with more than just physical liberty; it also encompassed the concepts of dignity, autonomy and privacy. She considered that an essential component of human dignity was the right to make certain fundamental personal decisions without interference from the state. She concluded that this aspect of the liberty interest provided women with a degree of autonomy to make decisions regarding reproduction, at least in the early stages of a pregnancy. In practical terms, this gave women the right to carry on with the pregnancy and reproduce, or terminate the pregnancy and not reproduce, at least during the early stages of the pregnancy.

It is important to note that Justice Wilson did not suggest that women had unlimited autonomy, but rather a degree of autonomy. She also restricted the woman's decision-making autonomy to the early stages of pregnancy, prior to foetal viability. Both she and Justice Beetz (and Estey J.) considered that at some point in the pregnancy, the state's interest in the developing fœtus would become compelling such that the state could limit the woman's rights.

Justice Wilson's interpretation of the section 7 liberty interest could be viewed as consistent with the articles in the CEDAW that provide women with rights to decide freely the number and spacing of their children. The CEDAW Committee's comments regarding these articles also supports such an interpretation. It states that a woman's decision respecting reproduction should not be limited by her spouse, parent or government.

---

[147] Elizabeth K. Spahn "Reproduction, Rights, and Reality: How Facts and Law Can Work for Women: Waiting for Credentials: Feminist Theories of Enforcement of International Human Rights" (1995) 44 Am. U.L. Rev. 1053 at 5 (Lexis Nexis).

[148] *Ibid.* "Privacy" has been recognized as an international human right since 1948 — in the *Universal Declaration of Human Rights*, article 12, and in article 8(1) of the European Convention on Human Rights (1950); "Equality" United Nations Charter, article 1(3) and the preamble – fundamental freedoms for all without distinction as to sex; and "Health" *Universal Declaration of Human Rights*, article 25(1) (Lexis Nexis).

The reproductive autonomy rights enunciated by Wilson J. in *Morgentaler, supra,* were with respect to a pregnant woman. Now that biotechnology has provided alternative means of conception, can reproductive autonomy be extended to protect decision-making with respect to an *in vitro* embryo?

Pregnant women and genetic testing of the embryo/fœtus

Pregnant women in Canada routinely undergo ultrasound tests during their pregnancy. These tests allow the physician to monitor the progress of the pregnancy and to detect abnormalities in the developing fœtus. In the case of women or couples who have a history of genetic disease, or when the woman is over the age of 35 years, physicians routinely recommend more sophisticated, invasive testing, such as chorionic villi sampling or amniocentesis, in order to detect the presence of any genetic anomaly in the fœtus.

These genetic tests are fundamentally private matters that provide crucial information about the health of the pregnant woman and of the fœtus that she carries. In Canada, pregnant women, in consultation with their physician, are able to choose to undergo such tests. If the tests revealed that the woman's health is at risk because of the pregnancy, or that the embryo or fœtus is severely deformed or carries a gene for a serious disease, the woman is free to choose to terminate the pregnancy and that right extends past the point of foetal viability.

In the event that the state prohibited such prenatal genetic testing, an argument could be made that the woman's liberty and security of the person interests, under the *Charter*, would be engaged. A woman's section 7 right to security of the person protects her physical and psychological integrity. A state prohibition could deprive her of crucial information about the health and genetic status of the fœtus. In those instances where a woman knows she is at risk of passing on a serious genetic disease to her child, the prohibition would arguably engage her psychological integrity by causing her profound and serious stress and anxiety. It would also interfere with her right to make a decision regarding the pregnancy. One could conclude that such a prohibition would engage the woman's liberty and security of the person interests under the *Charter*. Of course it would be open to the courts to determine that the prohibition was in accordance with the principles of fundamental justice, in which case there would be no *Charter* violation.

A woman and her *in vitro* embryos

The relevance of human rights is arguably more obvious and straightforward in the case of a pregnant woman whose body is implicated in the pregnancy. It may not be so clear, however, when the pregnancy has not yet begun and the embryo exists outside the woman's body, i.e., *in vitro*.

If the state prohibited a woman's right to access genetic information about her in vitro embryos through the use of PGD, would it raise any human rights issues?

One could argue that a prohibition on using PGD to obtain information necessary to make a decision about reproduction would engage the woman's liberty and the security of the person interests in section 7 of the *Charter*.

Recent Supreme Court jurisprudence has established that the right to autonomy to make decisions of a fundamentally personal nature, within the liberty interest, extends beyond the sphere of human reproduction to encompass a range of subject matters. Advances in biotechnology and assisted human reproduction make it possible for women to gain information about her embryos prior to pregnancy. Consequently, one could argue that an expanded liberty interest protects medical tests, such as PGD, on an *in vitro* embryo undertaken to provide the woman with critical information necessary for her to make a decision regarding reproduction. These activities undertaken on the very early embryo could be considered to fall within a "cluster of constitutionally protected choices."[149]

It is likely that genetic testing of one's *in vitro* embryos to select for reproduction only those that appear disease-free would qualify as a matter of fundamental personal importance that goes to the core of individual dignity and independence. This would be especially so if the person or couple were at risk of passing a genetic disease to their offspring. One could argue that a prohibition on the use of PGD would engage the woman's section 7 *Charter* right to liberty and to security of the person.

---

[149] *Litchez, supra,* note 74 at 15; *Carey, supra,* note 78 at 685.

What principle of fundamental justice would the court identify as a standard against which to measure the state's deprivation of the woman's section 7 rights?

In *Morgentaler, supra*, the Supreme Court identified procedural and substantive principles of fundamental justice against which to measure the state's deprivation of a woman's right to liberty, and found the deprivation breached the principles. The Court proceeded to consider whether the state could justify the deprivation under section 1 of the *Charter*. It is likely that the courts would proceed directly to the analysis under section 1 in the event of a challenge to the constitutionality of a prohibition on PGD.

Does the state have a compelling interest in the in vitro embryo that could justify infringing on a fundamental right?

Justice Wilson, in *Morgentaler, supra*, noted that the fœtus is potential life from the moment of conception. However, in balancing the state's interest in the protection of the fœtus as potential life under section 1 of the *Charter* against the woman's rights under section 7, she held that greater weight should be given to the state's interests in the later stages of the pregnancy. In fact, she noted that in the early stages of a pregnancy the state's interest in the developing embryo would be non-existent, while the woman's right to autonomy would be absolute.

Based on Wilson J's view of the fœtus as potential life from the moment of conception, one could argue that the *in vitro* embryo is potential life, however at this point the *in vitro* embryo could not be considered viable (it could not survive without artificial means).

An argument could be made that the use of PGD, as a diagnostic tool, would not engage the same compelling state interests as the use of prenatal diagnostic testing on the fœtus. If prenatal testing revealed a gene for disease in the fœtus, the woman could decide to terminate the pregnancy. If the fœtus had reached the point of viability, the state might argue that it has a compelling interest in the fœtus as potential and viable human life. However, PGD is conducted on an *in vitro* embryo that is only two or three days old. If PGD detected the presence of a gene for disease in the *in vitro* embryo, the woman could decide to let it perish. The *in vitro* embryo is clearly not viable; it is maintained through technology in a laboratory setting. In order to become viable, a woman must consent to transfer it into her womb and carry it into the second trimester of pregnancy.

The state may have an interest in the *in vitro* embryo as potential life, but since it is not viable, it is likely not sufficient or compelling enough to justify infringing on a woman's right to reproductive autonomy.

An argument could be made that the woman's right to physical and psychological integrity would be engaged by a prohibition on PGD. If a woman was denied access to PGD to obtain information as to the genetic status of her *in vitro* embryos, i.e., before pregnancy, her options would be restricted to sexual reproduction and prenatal testing of the fœtus once she is pregnant. If the prenatal testing indicates that the developing fœtus has a gene for a serious disease, the woman's choices are limited to a genetic abortion or the possibility of coping with a seriously ill or disabled child. The state prohibition on PGD could arguably cause her profound and serious psychological stress and anxiety implicating her security of the person interest. It could also interfere with her physical integrity, since there is an element of risk to the woman's physical integrity inherent in any abortion procedure. One might argue that the woman has been prohibited access by the state to what could be considered a beneficial medical procedure, i.e., PGD.

3.5.5.1 Conclusion

It is difficult to predict whether the provisions in international human rights and regional instruments could be referenced to support a broad definition of the right to reproductive autonomy under the *Charter*. The fact remains that, at the international level, procreational rights are not well defined. There are, however, basic principles and norms of international law that the courts could look to for assistance, such as privacy, equality and health. The courts might also be informed by U.S.

jurisprudence on reproductive autonomy developed under the *Bill of Rights.*

The Supreme Court has recognized that the liberty interest in section 7 of the *Charter* provides a degree of autonomy under which individuals are able to make decisions of fundamental personal importance without state interference.[150] A prohibition which deprived a woman, especially one at risk of passing on a genetic disease to her offspring, of the right to choose a procedure that would provide her with essential information to make an informed decision regarding reproduction would arguably engage her section 7 liberty interest.

Women would be limited to prenatal testing once they are pregnant as the only source of information with which to make a reproductive choice. Prenatal testing, such as amnioscentesis, is invasive and presents risks to both the mother and the fœtus, and could deprive the woman of her physical and psychological integrity. One could argue that the state prohibition on PGD would also engage a woman's section 7 *Charter* right to security of the person. A woman's options would be limited to prenatal testing, no testing, or a decision not to reproduce.

3.6 Issue 2: The right of parents to use PGD to select *in vitro* embryos based on certain favoured genetic traits

In the future, it may be possible for a parent to select an *in vitro* embryo based on certain traits that the embryo would exhibit as a child, such as hair or eye colour, height, and intelligence. Is the right to reproductive autonomy broad enough to protect a woman's choice of PGD to select *in vitro* embryos on the basis of certain favoured genetic traits?

The following discussion is limited to three genetic traits that science is currently able to identify through PGD. These traits are: (1) a gene for deafness, (2) a desired sex, and (3) genetic compatibility to donate to a sibling who has a life-threatening disease.

3.6.1 A Gene for Deafness

If one has the right to use PGD to select only those in vitro embryos that are disease free, does one have a corresponding right to choose PGD to select for reproduction an *in vitro* embryo because of the presence of a certain genetic anomaly? In 2002, the Journal of Medical Ethics reported that a deaf lesbian couple in the U.S. used sperm from a donor with five generations of deafness in his family to self-inseminate with the objective of giving birth to a deaf child.[151]

The article questions whether there might be some good reasons for allowing couples to select for disability. The author notes that in the case above, there were no ethical issues raised because the couple had the right to reproduce with whomever they chose. They chose to reproduce with a man who had a long family history of genetic deafness.

Not everyone would agree that this act is devoid of ethical considerations. The fact that the women consciously selected a sperm donor with a long family history of deafness in the hope of creating a deaf child might, for some individuals, raise significant ethical and moral issues.

Julian Savuleseu, as well as other commentators, questions whether a woman or couple have caused any harm when they make such as choice. In the view of one commentator, to be harmed, the child would have to be put in a worse condition than it would have otherwise been in.[152] However, if the child had not been chosen by the women for reproduction on the basis of deafness, he or she would not have been born.[153] The article notes that there are other deaf couples who would like to choose PGD to select a deaf child. For these prospective parents, deafness is not considered a disability but rather as a distinct culture that welcomes deaf children.[154]

---

[150] *Morgentaler, supra* note 109. The Supreme Court, in three separate majority decisions, found that both security of the person and liberty (the decisions of Beetz and Wilson) included rights to make decisions affecting one's physical and psychological integrity, and the right to make decisions of fundamental personal importance free from state interference.

[151] Julian Savuleseu, Director, Oxford Centre for Applied Ethics "Deaf lesbians, "designer disability," and the future of medicine" (2002) Journal of Medical Ethics 325 at 1 (http:jme.bmjjournals.com).

[152] Shaun D. Pattinson "Wrongful Life Actions as a Means of Regulating Use of Genetic and Reproductive Technologies (1999) 7 Health L.J. 19 at 5 (Lexis Nexis).

[153] *Ibid.* at 3 (Lexis Nexis).

The purpose of genetic testing is generally to offer individuals or couples the opportunity to select the child with the "best life prospects." Who decides, however, what are the best life prospects? Whose value judgements should prevail? In at least one author's opinion, reproductive freedom and respect for autonomy are such that the value judgements of the parents should prevail, as long as their decision does not harm the child.[155]

Not all commentators agree. Some argue that because there are significant disadvantages associated with many disabilities, it is unethical to allow parents to deliberately choose a characteristic or trait in a child that is treated by society as a disability or disadvantage.[156]

However, on close analysis, this argument is flawed. The deaf women who chose to use PGD to select from among their *in vitro* embryos only those with the gene for deafness, were not engineering deafness in the embryo but rather were selecting for reproductive purposes only those *in vitro* embryos that already possessed the gene for deafness. If the *in vitro* embryo had not been selected for reproduction, it would not have experienced life. The question remains: Is the child worse off being born deaf or never having been born at all?

If the state prohibited the use of PGD for such a purpose, would it raise any human rights issues? The answer to this question depends very much on the scope given by the courts to reproductive autonomy under section 7 of the *Charter*. If the courts considered that the information obtained from PGD as essential to allow the woman to make a decision respecting reproduction, then the prohibition could arguably be found to engage a woman's section 7 liberty and security of the person interests.

Such a prohibition might also raise human rights issues related to equality under section 15 of the *Charter*. Section 15(1) provides that:

> Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or *physical disability*. [emphasis added]

The deaf women might argue that the state prohibition on PGD to select *in vitro* embryos because they have a particular genetic anomaly, in this case deafness, is discriminatory on the basis of an enumerated ground, i.e., physical disability. Other women in Canada can choose to undertake PGD to select only those *in vitro* embryos for reproduction that are without the gene for deafness. An argument could be made that the state prohibition on PGD impacts negatively on the deaf woman's human dignity.

The concerns and analysis might be much different if a woman wanted to choose genetic engineering to create deafness in an *in vitro* embryo. A discussion of the possible human rights issues relating to genetic engineering have not been addressed in this paper.

3.6.2 A Desired Sex

The desire to have some control over the gender of one's offspring has existed far longer than AHR technologies, such as PGD. However, the use of these technologies (developed to assist the infertile to reproduce) for social sex selection raises for some individuals both moral and ethical concerns.[157]

In Canada, the Royal Commission's national survey noted that, with respect to sex-selection:

> ...contrary to what has been found in some other countries, a large majority of Canadians do not prefer children of one sex or the other. Many interveners... assumed that Canadians have a pro-male bias with regard to family composition; we found that this assumption appears to be unfounded...[158]

---

[154] Savuleseu, *supra* note 151 at 2.

[155] *Ibid.* at 4.

[156] Rebecca Knox "Preimplantation Genetic Diagnosis: Disease Control or Child Objectification?" (2003) St. Louis U. Pub. L. Rev. 435 at 6-7 (Lexis Nexis).

[157] Ethics Committee of the American Society of Reproductive Medicine, "Sex Selection and Preimplantation Genetic Diagnosis" (1990) 72 (No. 4) Fertility and Sterility 595 at 597.

[158] *Supra* note 3 at 889.

The AHR Act prohibits the use of PGD to select for reproduction purposes *in vitro* embryos of a particular favoured sex (section 5 (1)(e)). The Act does permit the use of PGD to select embryos on the basis of sex when the intent is to prevent a sex-linked disorder or disease; this activity will be controlled under the Act.

As noted earlier, in the U.K., selecting an *in vitro* embryo on the basis of its sex for non-medical reasons is prohibited under the *HFE Act*.

The Ethics Committee of the American Society of Reproductive Medicine ("Committee") provides standards of practice for physicians and obstetricians. Compliance with the standards is voluntary. In 2002, the Committee restated its position with respect to the use of PGD for social sex selection.

The Committee recommended that: (a) initiating *in vitro* fertilization and PGD for the purposes of social sex selection of *in vitro* embryos in the case of a first born should be discouraged by physicians; and (b) initiating *in vitro* fertilization and PGD for social sex selection in order to create gender variety in a family should also be discouraged.[159] The Committee did not go so far as to recommend that such practices be prohibited by state or federal law. This may be because the Committee subscribes to a broad interpretation of the constitutional right to procreational autonomy.

There are women and couples who would like to use PGD to select for reproduction only those *in vitro* embryos that are of a particular sex. Some of the reasons given by Canadians, and others, for selecting *in vitro* embryos on the basis of sex include: to bear and raise children of the culturally preferred sex; to ensure economic usefulness within the family; to achieve gender balance or variety among children in a given family; and to determine a gendered birth order.[160] Proponents of social sex selection argue that it is a logical extension of the right to procreate and reproductive autonomy.

Some argue that selecting for sex is a lesser evil than the alternative of prenatal genetic testing of the fœtus followed by an abortion, and far better than the alternative of infanticide, which is still practiced in some countries.[161] In addition, there are those who argue that the use of PGD for sex selection could contribute to population control.[162]

At least one commentator has argued that the ability to use PGD to select only those *in vitro* embryos of a particular sex might be a useful tool in family planning and population control. If parents were able to select a child of each sex, they might not continue to reproduce in the hope of having a child of a particular sex.[163]

Some commentators have argued that the legal doctrine of informed consent with respect to medical treatment may justify a woman's claim to information relating to the sex of the fœtus she bears. This argument might also apply to give a woman a legal right to the information concerning the sex of the *in vitro* embryos being transferred into her for the purpose of reproduction. The stated counter argument is that such a right to information should be restricted to only the information necessary to make a choice on medical grounds, such as the genetic health of the fœtus. [164]

Opponents of this use of PGD cite the following concerns: the practice will result in gender discrimination and gender bias in society as a whole; the appropriateness of expanding control over nonessential characteristics of offspring; and the relative importance of sex selection when weighed against medical and financial burdens to parents and against multiple demands on limited medical resources.[165] They argue that procreational autonomy and privacy rights should not be extended to include a parent's right to choose PGD to select the sex of their children. These rights should not be considered fundamental by the court, so as to ensure that the state can prohibit and regulate such practices. The state could likely establish that such a prohibition or regulation is rationally related to a legitimate government purpose.[166]

---

[159] Roberts, *supra* note 12 at 6.

[160] *Supra* note 157.

[161] Rebecca J. Cook, Bernard M. Dickens and Mahmoud F. Fathalla, *Reproductive Health and Human Rights* (New York: Oxford University Press, 2003) at 367.

[162] *Supra* note 157 at 596.

[163] *Ibid.* at 595.

[164] Cook, *supra* note 161 at 367.

[165] *Supra* note 157 at 596.

[166] Kelly M. Plummer "Ending Parents' Unlimited Power to Choose: Legislation is Necessary to Prohibit Parents' Selection of Their Children's Sex and Characteristics" (2003) 47 St. Louis L.J. 517 at 4 (Lexis Nexis).

Furthermore, opponents are concerned that social sex selection could psychologically harm children selected on the basis of their sex since it would place high expectations on them. It is argued that this practice would reduce a child to a consumer product. Selecting a child on the basis of sex is not a proper criterion: children should be valued for their own sake, and not selected and valued primarily because of their sex.[167] In addition, opponents argue that if widely practiced, it could lead to an overall change in the human sex ratio which would be detrimental to the future of society.[168]

One could argue that the prohibition on PGD for non-medical sex-selection in the AHR Act denies a woman access to information necessary for her to make a decision regarding reproduction, and thus engages her liberty and security of the person interests under section 7 of the *Charter*. A distinction could, however, be made between accessing information as to the sex of the embryo and accessing information as to the presence of a gene for disease in the *in vitro* embyro. The courts might find that only the latter type of information can be categorized as central to a person's decision regarding reproduction and thus protected. With respect to information as to the sex of a future child, the court may consider decisions based on this type of information as more of a "lifestyle" choice,[169] than a decision respecting a matter that goes to the core of individual dignity and independence.

The provisions regarding the right to found a family and family planning in the CEDAW and the ICCPR might inform the courts when it interprets the scope of the *Charter* right to reproductive autonomy. The courts might be particularly influenced by the non-discrimination provisions in article 5(a) of CEDAW when interpreting the scope of reproductive autonomy, at least with respect to non-medical sex selection. The courts may find that a state prohibition against sex selection for social or cultural reasons is in accordance with the principles of fundamental justice or is justifiable by the state under section 1 of the *Charter*.

3.6.3 A Donor Child

Through the use of PGD and tissue-typing, it is possible to select for and transfer only those *in vitro* embryos that have certain traits needed to provide a cell or tissue transplant for a seriously ill sibling, without harming the donor child.

It has already been noted that, under the UK's *HFE Act*, parents can access both *in vitro* fertilization and PGD to create a donor child. The UK court has held that the HFE Authority has the power under the *HFE Act* to issue licences for this procedure. It should be noted that each case is considered on its merits by the HFE Authority before it issues an approval for a particular procedure and there have been cases where the HFE Authority has refused to issue a licence.[170]

The AHR Act does not prohibit the use of PGD or tissue-typing. Until such time as the Agency is created and able to inspect, only those fertility clinics that conducted PGD in the year preceding the Act's coming into force can continue to do so without a licence. Once the Agency is created, a physician or clinic would have to obtain a licence from the Agency to perform *in vitro* fertilization and perhaps a second licence or approval to conduct PGD with tissue-typing. The procedure would most likely be regulated under the Act.

Some commentators argue that creating a child to be a future donor is unethical and represents an immoral objectification and commodification of the child. In addition, the child may suffer psychological harm on learning that they were created and chosen in order to save a sibling.[171]

---

[167] *Ibid.* at 15 (Lexis Nexis).

[168] *Supra* note 157 at 596; Susan M. Faust "Baby Girl or Baby Boy? Now You Can Choose: A Look at New Biology and No Law" (2000) 10 Alb. L.J. Sci. & Tech. 281 at 5 — The author sites the results of a recent survey in Ohio that suggest the preference for male babies may be weakening. Although the survey finds some support for a sex preference in the birth order of children, the majority of participants indicated that they had no preference for a boy or girl as the first-born child. She notes that as almost 50% of pregnancies in the U.S. are unplanned, it is likely that only a minority of couples would actually use sex selection and this minority would be unlikely to create a significant sex ratio imbalance.

[169] *Malmo-Levine*, *supra*, note 129 at para. 86.

[170] RG Edwards (Editor), Reproductive BioMedicine Online "Ethics of preimplantation diagnosis: recordings from the International Symposium on Preimplantation Genetics" 2002 at 3. Online: http://www.rbmonline.com.

[171] Knox, *supra* note 156 at 8-9.

Other academics point out that parents have always had reasons for creating children, many of which could be viewed as selfish, such as to provide companionship, to assist with a family business, or to care for parents as they age. Creating a child to save the life of an existing sibling is no more psychologically damaging to the child than other more common reasons for procreation. Many parents have conceived a second child without the use of technology in the hopes that the child will be a tissue match for an already existing sibling who is ill. The use of *in vitro* fertilization and PGD to create such a child could be viewed simply as eliminating a large part of the uncertainty and stress for these parents.[172]

It is interesting to note that the UK Court in *Quintavalle, supra,* interpreted the *HFE Act* in a broad manner such that the HFE Authority has the power to authorize the creation of a donor child. The UK Court's decision was not based on the parent's right to procreational autonomy; rather it was the result of the application of principles of statutory interpretation to the *HFE Act.*

An argument could be made that a prohibition on the use of PGD to obtain information to select an *in vitro* embryo to become a donor child is more than just a decision respecting a lifestyle choice, it deprives the woman of critical information to make a decision relating to reproduction. Not only would the prohibition engage the woman's section 7 liberty and security of the person interests, it would arguably engage the interests of the ill sibling to life and security of the person under section 7. The state prohibition would prevent the existing sibling from accessing a beneficial medical treatment, e.g. a transplant of histocompatible stem cells from a saviour child, for a condition that may pose a threat to his or her life.

3.6.4 Conclusion

In those cases where the prohibition is backed by offence provisions that include the possibility of jail, section 7 interests are engaged. With respect to the creation of a donor child, the interests and human rights raised by a prohibition on PGD are those affecting the woman and the ill sibling. The sibling may argue that if the state prohibits his mother access to the necessary information to choose an embryo for reproduction that will become a donor child, his or her s. 7 *Charter* rights to life and security of the person are engaged.

With respect to non-medical sex selection, the courts might consider that this information is not central or is irrelevant to a decision respecting reproduction. On the other hand, the courts might consider information as to the presence of a gene for disease, or genetic compatibility with an existing ill sibling, as central to reproductive decision-making. A state prohibition on accessing the latter type of information for reproductive decision-making could engage a woman's liberty and security of the person interests protected by the *Charter.*

If the courts look to international human rights instruments, such as the CEDAW and the ICCPR, they might be persuaded to broaden reproductive autonomy under s. 7 of the *Charter* to include a right to access certain essential information to make a choice regarding reproduction, free from state interference. The courts could look to U.S. constitutional jurisprudence, as it periodically does when interpreting *Charter* rights, to inform its interpretation of procreational autonomy.

3.7 Issue 3: The *In Vitro* Embryo

3.7.1 The Right to Life

No Canadian legislation guarantees an embryo or fœtus the right to life.[173] In Canada, as in most western countries, the prevailing view of the legal status of the embryo is that it is *sui generis.* The embryo is deserving of respect, but not the legal rights that come with personhood. The embryo or fœtus is not viewed as equivalent to that of a child for many reasons, including the lack of developmental individualism and sentience.

The Supreme Court has held that an *in utero* embryo and a fœtus are not persons under the law and thus have no legal rights. However, once the fœtus is born alive, his or her legal rights crystallize and for certain purposes, such as tort law, the law may recognize that the child existed before birth. Because the *in utero* embryo and fœtus have no legal rights, they are not considered to have a right to life. However, the state's interest in the fœtus as a potential human being may increase as it develops within the womb. Once the fœtus is viable outside the womb, which may be sometime in the second trimester of the pregnancy, the state may be able to justify legislating to protect it (*Morgentaler, supra*).

---

[172] *Ibid.* at 8

[173] See Chapter 2 for a more detailed discussion.

Based on the existing jurisprudence, an *in vitro* embryo existing as it does outside a woman's body would likely be assigned the same non-person status as an *in utero* embryo and fœtus by the courts, and thus be found to possess no legal rights until after it is born alive. The courts would likely find that an *in vitro* embryo does not have a right to life.[174]

3.7.2 The Right to Be Born With a Sound Mind and Body

Does a child have a legal right to be born with a sound mind and body? Do parents have a corresponding ethical or legal obligation to give birth to only genetically healthy children? If there is such a legal right, could it evolve into a human right?

3.7.2.1 International and Regional Instruments

In 1991, Canada ratified the United Nations' *Convention on the Rights of the Child*[175] ("CRC").[176] The CRC sets out a number of important rights and protections for children.

Article 24(1) and (2) of the CRC states:

Article 24

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

   a. To diminish infant and child mortality;

   b. To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;

   c. *To combat disease* and malnutrition, including within the framework of primary health care, *through, inter alia, the application of readily available technology* and through the provisions of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;

   d. To ensure *appropriate pre-natal* and post-natal *health care for mothers;*

   e. To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

   f. To develop *preventative health care*, guidance for parents and family planning education and services. [emphasis added]

It is of interest to note that the Preamble to the CRC notes that "…the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, *before* as well as after birth."[177] [emphasis added]

---

[174] For a detailed discussion on the international approach, and the approach of Canada and other jurisdictions to the right of an *in vitro* embryo to life, see Chapter 2 of the project paper at 40 to 44.

[175] United Nations *Convention on the Rights of the Child*, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), *entered into force* September 2, 1990.

[176] Catherine Covell and R. Brian Howe, *The Challenge of Children's Rights for Canada* (Waterloo: Wilfrid Laurier University Press, 2001) at 15.

[177] *Supra* note 175 (preamble).

The CRC defines "child" in Article 1 as "every human being below the age of eighteen years unless, under the law applicable to the child, majority is attained earlier."[178] The *Travaux Préparatoires* to the CRC noted that the original wording of Article 1 was "...a child is every human being from the moment of his birth to the age of 18 years unless, under the law of his state, he has attained his age of majority earlier."[179]

The *Travaux Préparatoires* also noted that there was "considerable debate" at the third meeting of the Working Group concerning the definition or concept of a "child." Some delegates argued that such a definition would be contrary to the law of their state which defines childhood as beginning at the moment of conception. Other delegates suggested that, to avoid conflict, any reference to the beginning point of childhood in the Article should be abandoned and instead wording should be chosen that would be compatible with the variety of domestic legislation on the issue.[180]

The current wording of the Article might allow those countries that consider childhood to begin at the moment of conception to interpret the rights in the CRC for domestic purposes to apply from the moment of conception onwards. The *Travaux Préparatoires*[181] noted that Article 24(2)(d) was amended by the representative of the UK to read "ensure appropriate pre- and post-natal health care for mothers and their children."[182] The Article was further amended by the representative from the U.S. to drop the reference to "their children" so that it read "to ensure appropriate pre- and post-natal care for mothers."[183] The U.S. amendment was likely prompted by a desire to avoid conflicts between the rights of an embryo/fœtus and those of the pregnant woman.

In the context of genetic testing and therapies, some commentators suggest that the language of both the UDHR and the ICESCR support a view that the right to enjoy the benefits of scientific progress and its applications belong to the embryo rather than the future parents. They argue that the embryo has a right to benefit from genetic testing, such as PGD and germ-line manipulation, because of the emphasis on individual well-being. It presumes a right to be free from the suffering that genetic technology can prevent.[184]

Cook, et al. suggests that, with respect to an individual's or couple's access to *in vitro* fertilization and PGD, the most obvious human right implicated would be the right to the benefits of scientific progress. [185] The authors argue that this right serves the goal of other human rights, such as the right to found a family, and the right for both a future child and the parents to have the highest attainable standard of health. With respect to the future child, this would relate primarily to their physical health. However, with respect to the parents, this would include both mental health and social well-being.[186]

3.7.2.2 The Law in Other Jurisdictions

In common law jurisdictions, if not barred by statute, a number of different tort actions can be undertaken by children or parents injured prior to birth or during birth, depending on whose interests were affected. Three such tortious causes of action are: preconception torts, the tort of wrongful birth, and the tort of wrongful life. A "preconception tort" occurs when a child, born alive, is harmed prior to or during its birth by the wrongful, preconception conduct of someone other than its parents.[187] Parents may make a claim for "wrongful birth" if the birth of an unplanned child occurs.[188] This is because the parent's right to control their own reproduction has been denied by the tortious conduct of another person.[189] An action for wrongful life is a claim by a person born with a predictable physical or mental disability that, but for the defendant's breach, the person would not have been conceived or born.[190]

---

[178] *Ibid.* at article 1.

[179] Sharon Detrick (Editor), *The United Nations Convention on the Rights of the Child: A Guide to the Travaux Preparatoires"* (The Netherlands: Martinus Nijhoff Publishers, 1992) at 115.

[180] *Ibid.* at 115.

[181] *Ibid.* at 343 to 359.

[182] *Ibid.* at 357.

[183] *Ibid.* at 357.

[184] Maha F. Munayyer, "Genetic Testing and Germ-Line Manipulation: Constructing a New Language for International Human Rights" (1997) 12 Am. U.J. Int'l. & Pol'y 687 at 5 (Lexis Nexis).

[185] Rebecca Cook, Bernard Dickens and Mahmoud F Fathalla, *Reproductive Health and Human Rights: Integrating Medicine, Ethics and Law* (Oxford: Oxford University Press, 2003) at 359.

[186] *Ibid.*.

[187] Elizabeth F. Collins "An Overview and Analysis: Prenatal Torts, Preconception Torts, Wrongful Life, Wrongful Death, and Wrongful Birth: Time For a New Framework" (1984) 22 J. Family Law 677 at 677-78.

[188] *Ibid.* at 678.

[189] *Ibid.*

This section examines the current status of a cause of action for "wrongful life" and whether there is a right to be born with a sound mind and body.

The U.S.

On April 1, 2004, President Bush signed into law the *Unborn Victims of Violence Act of 2004*.[191] The Act provides, among other things, that any person who intentionally kills or attempts to kill a child *in utero* (in the mother's womb), shall be punished for intentionally killing or attempting to kill a human being.[192] However, the Act clarifies that the following persons are not subject to prosecution: a person performing an abortion for which the pregnant woman has consented, a person providing medical treatment to the pregnant woman or her unborn child, and the pregnant woman (amendment to article 119a).

Although there is no federal or state law granting a child the right to be born with a sound mind and body, there is a growing body of jurisprudence that recognizes a child's right to sue their parents and third parties for prenatal and preconception torts and, in approximately three states, for the tort of wrongful life. In an action for wrongful life, the plaintiff child typically contends that had the defendant given the mother timely warning of the risk of congenital abnormality, she would have chosen not to conceive the child, or if the negligence is asserted to have occurred after conception, the mother would have chosen to abort the embryo/fœtus. There is no suggestion that the defendant caused the child's disability. Instead, the assertion is that but for the defendant's omission, the child would not have been born and would have been spared a life of physical or mental incapacity, pain and suffering.[193] To date, there are only a handful of states in the U.S. that recognize this cause of action.

The U.S. courts have recognized preconception tort claims on the part of children since the 1970s.[194] In these cases, the courts have essentially recognized a duty of care to future persons.[195] The courts that have refused to recognize such a duty generally take the view that the policy implications that arise from the duty are so momentous that the decision to extend liability in this manner must be left to the elected legislature.[196]

Preconception tort claims have arisen most often in the context of medical malpractice. For example, in *Bergstreser v. Mitchell*,[197] the Circuit Court of Missouri permitted the plaintiff child to recover for injuries caused as a result of a physician's negligence when he performed surgery on the plaintiff's mother before the plaintiff was conceived. The physician's negligent surgery on the mother caused the yet-to-be conceived child's injuries.

Preconception tort claims have also succeeded in the areas of rubella immunization, pharmaceutical products, motor vehicle accidents, and toxic substances. One commentator has suggested that the emergence of AHR technologies, as well as the possibility of preconception gene therapy, makes it likely that the court will face an influx of preconception tort claims arising from these activities.[198]

In addition, there is a growing body of common law recognizing a child's action for damages for wrongful life based on the child's legal right to be born with a sound mind and body. *In the Matter of Baby X*,[199] is a case that involved a tort action by the child against his mother for prenatal neglect because she was addicted to narcotics during the pregnancy. The child suffered postnatal drug withdrawal. The Michigan Court of Appeal noted that:

> While there is no wholesale recognition of fetuses as persons…fetuses have been accorded rights under certain limited circumstances…This limited recognition of a child *en ventre sa mere* as a child *in esse* is appropriate when it is for the child's best interest.

---

[190] Bernard M. Dickens, "Wrongful birth and life, wrongful death before birth, and wrongful law", in Sheila A. M. McLean, ed., *Legal Issues in Human Reproduction* (Aldershot, England: Gower Publishing Company Limited, 1989) at 83.

[191] The *Unborn Victims of Violence Act of 2004*, Chapter 90(a) — Protection of Unborn Children, sec. 1841. Online: http://news.findlaw.com.

[192] *Ibid.* at s. 1841(2)(e)

[193] Philip H. Osborne, *The Law of Torts*, 2nd ed. (2003) (D. Human Reproduction) at 2 (QL).

[194] Matthew Browne "Preconception Tort Law in an Era of Assisted Reproduction: Applying a Nexus Test for Duty" (2001) 69 Fordham L. Rev. 2555 at 1 (Lexis Nexis).

[195] *Ibid.* at 1 (Lexis Nexis).

[196] *Ibid.* at 4 (Lexis Nexis).

[197] *Bergstreser v. Mitchell*, 577 F.2d 22 (8th Cir. 1978).

[198] Browne, *supra* note 191 at 21 (Lexis Nexis).

[199] *In the Matter of Baby X*, 97 Mich. App. 111; 293 N.W.2d 736 (Mich. Ct. App. 1980) (Lexis Nexis).

> *Since a child has a legal right to begin life with a sound body and mind*…we believe it is within this best interest to examine all prenatal conduct bearing on that right."[200] [emphasis added]

The Court held that the mother's prenatal conduct was sufficient cause to allow the probate court to assert jurisdiction and to order a custody hearing. In this case, the Court based its decision on the child's best interest and the child's legal right to be born with a sound mind and body.[201]

In *Turpin v. Sortini*,[202] a child born deaf sued her mother's physicians for not diagnosing her sister's hereditary deafness in time to permit her mother to decide not to conceive her. The child sought damages for being "deprived of the fundamental right of a child to be born as a whole, functional human being without total deafness."[203] Despite the fact that the duty of the physician was originally owed to the plaintiff's sister, the Supreme Court of California allowed the child plaintiff's claim and awarded her extraordinary expenses over her lifetime for specialized teaching, training and hearing equipment, while disallowing the claim for general damages.[204]

The Court noted:

> …if medical knowledge were such that a fetus could be treated prior to birth to cure or alleviate the hereditary defect in question. Under those circumstances, Joy [the plaintiff] could properly claim that if defendant had not negligently failed to diagnose the hereditary problem, she could have been treated *in utero* and been born as a healthy or less impaired child. Such an advance in medical science would thus make this case analogous to the prenatal injury decisions….[205]

In *Curlender v. Bio-Science Laboratories*,[206] a child sued a medical testing laboratory and a physician on the basis of wrongful life because the child was born with Tay-Sachs disease (a life-threatening hereditary genetic disease). The parents also sued alleging that the defendant had negligently performed blood tests on them resulting in "incorrect" information as to their status as carriers, and resulting in the birth of a mentally retarded child with serious medical problems and a four-year life expectancy.[207] The California Court of Appeal awarded the child damages for pain and suffering and any special pecuniary loss resulting from his impaired condition. The Court referred with approval to another wrongful life case in which the court had noted:

> …decisional law must keep pace with expanding technological, economic and social change. Inherent in the abolition of the statutory ban on abortion…is a public policy consideration which gives potential parents the right, within certain statutory and case law limitations, not to have a child. This right extends to instances in which it can be determined with reasonable medical certainty that the child would be born deformed. The breach of this right may also be said to be tortious to the *fundamental right of a child to be born as a whole functional human being*.[208] [emphasis added]

In *Grodin v. Grodin*,[209] a child sued both his mother and her physician. He sued his mother for her negligent failure to seek proper prenatal care. She failed to request a pregnancy test from her physician and failed to inform him that she was taking the drug tetracycline, which caused the child's teeth to be discoloured. The Michigan Court of Appeal recognized the child's legal right to "begin life with a sound mind and body," and ruled that the mother could be liable for such failures if they were found to be unreasonable with respect to the magnitude of the risk.[210]

---

[200] *Ibid.* at 2 (Lexis Nexis).

[201] *Ibid.* at 3 (Lexis Nexis).

[202] *Turpin v. Sortini*, 31 Cal.3d 220; 643 D.2d 954 (Supreme Court of Cal. 1982) (Lexis Nexis).

[203] *Ibid.* at 8.

[204] Penelope Watson "*Edwards v. Blomely; Harriton v. Stephens; Waller v. James:* Wrongful Life Actions in Australia" (2002) 26 Melbourne U. L.R. 736 at 7 (Lexis Nexis).

[205] *Turpin, supra* note 199 at 8.

[206] *Curlender v. Bio-Science Laboratories*, 106 Cal.App.3d 811; 165 Cal. Rptr. 477 (Cal. Ct. App. 1980) (Lexis Nexis).

[207] *Ibid.* at 3.

[208] *Ibid.* at 7, referring to *Park v. Chessin* (1977) 60 App. Div 2d 80 [400 N.Y.S 2d 110].

[209] *Grodin v. Grodin*, 301 N.W.2d 869 (Mich. Ct. App. 1980) (Lexis Nexis).

[210] *Ibid.* at 870 and 871.

Germany

In Germany, both the *in vitro* and *in utero* embryo are assigned rights from the moment of conception. The *Embryo Protection Law* permits only those activities on the embryo that are for its preservation and protection. Abortion, although illegal in Germany, has been permitted by the Constitutional Court to be performed until fourteen weeks gestation but only after the woman has undergone counselling.[211]

Despite Germany's legislative scheme giving protection and assigning rights to the *in vitro* embryo, it is unlikely that Germany would condone PGD and genetic therapies to improve the life chances or the health of an *in vitro* embryo. Germany's position may be seen as contradictory by some. It is understandable, however, given the concern that allowing PGD, genetic manipulation, and alteration would result in a eugenics movement reminiscent of what occurred in Germany before and during World War II.

The U.K.

In 1976, the U.K. passed the *Congenital Disabilities (Civil Liability) Act* which imposed certain limits on the rights of a child born disabled to sue in negligence for injuries that occurred prenatally. The *Act* exempts a mother from tort liability for prenatal negligence to her children who are born alive. However, the exemption does not apply to prenatal negligence that occurs when the pregnant woman is in breach of her general duty of care while driving a motor vehicle.

McKay et al. v. Essex Area Health Authority et al.[212] ("*McKay*") was the first "wrongful life" claim brought in the U.K. and in the British Commonwealth. In this case, the infant plaintiff was born severely disabled because her mother contracted rubella during the early stages of pregnancy. The child brought a claim for "wrongful life" against the physician and the Essex Authority.

The Court concluded, relying in part on a report by the U.K. Law Commission, that the *Congenital Disabilities Act 1976* deprived any child born after its passing of a cause of action for "wrongful life."[213] Since this was the first case in which a court in the UK or the Commonwealth had to consider this cause of action, it gave further reasons for striking out the claim.

While the three judges of the Court were unanimous as to the disposition of the case, they each gave separate reasons. The most oft-quoted reasons are those of Stephenson L.J. He noted that the physician was under a duty to advise the mother of her right to have an abortion after contracting rubella. However, the physician owed no such duty to the child. In his view, imposing such a duty would make a "further inroad on the sanctity of human life which would be contrary to public policy. It would mean regarding the life of a handicapped child as not only less valuable than the life of a normal child, but so much less valuable that it was not worth preserving."[214]

Furthermore, Stephenson L.J. found it impossible in a case for wrongful life to make an award of damages. He noted:

> To measure loss of expectation of death would require a value judgment where a crucial factor lies altogether outside the range of human knowledge and could only be achieved, if at all, by resorting to the personal beliefs of the judge who has the misfortune to attempt the task. If difficulty in assessing damages is a bad reason for refusing the task, impossibility of assessing them is a good one…I would regard it on principle as disclosing no cause of action.[215]

McKay is considered by many courts in common law jurisdictions as the leading case on wrongful life.

In 1990, the U.K. passed the *HFE Act*. Section 44 of the *HFE Act* amended the *Congenital Disabilities (Civil Liability) Act, 1976*, by extending liability to cover AHR procedures. Section 44 amended the *Congenital Disabilities Act* with the following addition in section 1:

---

[211] Questions and Answers about Germany, "Health Care, Health Issues and Social Welfare" (2001) at 1 Online: http://www.germany-info.org/relauncy/info/facts/facts/questions_en/he.../healthissues3.htm

[212] *McKay et al. v. Essex Area Health Authority et al.* [1982] Q B 1166 (Court of Appeal) (Lexis Nexis).

[213] *Ibid.* at 3 and 8.

[214] *Ibid.* at 10.

[215] *Ibid.* at 11.

1A. (1) In any case where –

> a. a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled,
>
> b. the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and
>
> c. a person is under this section answerable to the child in respect of the act or omission,

the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.

Some Commentators suggest that, with the passage of this amendment, the U.K. Parliament has opened the door to wrongful life claims by children born with a preventable disability or disorder. It permits an "action by the child for the negligent selection of an embryo and thus for claims of 'wrongful life'."[216] It would allow a child, created through AHR and born with a disability, to sue the person responsible for damages where the disability resulted from an act or omission in the selection, storage or use of the *in vitro* embryo. This might include a failure to undertake PGD and a failure to select for transfer only those *in vitro* embryos that were free of a particular genetic disease. This would be especially so where one or both of the biological parents had a family history of the disease.

To date, only one action has been brought under the amended provisions of the *Congenital Disabilities Act* and it was settled. In *Heath v. Bromley Health Authority*,[217] the parents of children born with disabilities sued the Bromley Authority on behalf of their children for the harms suffered as a result of being born premature. The parents alleged that the Authority's negligent pre-conception treatment and monitoring of the mother during fertility treatments in 1992 resulted in the premature births. Although the Authority knew that the mother was carrying multiple fœtuses, information respecting warnings and risks associated with multiple pregnancy were not disclosed to the parents.

The case was settled out of court. Mr. Justice Leveson approved the settlement of all the claims of liability. The Bromley Authority admitted breach of its duty to the parents in relation to their wrongful conception claim. Although the Authority agreed to the settlement of the children's claims, it did not admit to liability.

3.7.2.3 Academic Literature and Commentary

The following discussion primarily refers to American literature and commentary. The case law in the U.S. is the most evolved with respect to prenatal and preconception torts. Furthermore, unlike other common law jurisdictions, claims for wrongful life have been allowed in a number of U.S. states. These judicial developments have spurred controversy and an abundance of commentary.

Some American academics have suggested that children may have an emerging right to be born free of genetic disabilities. They have suggested that this emerging "right" may become more prominent given the limited resources for health care and a growing public view that individuals have a social responsibility to take the necessary preventative steps in their private lives so as not to unduly burden public budgets.[218]

Other commentators have argued that women may have an obligation to undergo prenatal screening when there is a known risk of passing a genetic disease to the child. Once such testing and screening becomes less risky and invasive (as it most likely will) and widely available, mandatory testing for serious genetic anomalies may be a practice the government would consider adopting. In the view of at least one American commentator, it would likely withstand a challenge under the *U.S. Constitution*.[219]

---

[216] Shaun D. Pattison, "Wrongful Life Action as a Means of Regulating Use of Genetic and Reproductive Technologies" (1996) 7 Health L.J. 19-32 at 11 (Lexis Nexis); I. Kennedy & Grubb, *Medical Law: Text with Materials*, 2d. ed. (London: Butterworths, 1994) at 977.

[217] *Heath v. Bromley Health Authority* (unreported, High Court (2001)).

[218] Lois Shepherd "Protecting Parents' Freedom to Have Children with Genetic Differences" 1995 U. ILL. L. Rev. 761 at 3 (Lexis Nexis).

[219] *Ibid.* at 8 citing John A. Robertson "Procreative Liberty and the Control of Conception, Pregnancy and Childbirth" (1983) 69 VA. L. REV. 405 at 425.

To override constitutionally guaranteed rights of liberty and privacy, the state interest would have to be found to be compelling. It has been suggested that such an interest would be found where it provided women with the "necessary" information to decide whether to abort an affected foetus, or to prepare for the birth of a child in order to maximize the child's well-being.[220]

Furthermore, it has been suggested that perhaps there is a "conditional prospective foetal right." This right would belong to and would protect only those foetuses whose mother or parents intend to bring them to term. Some U.S. courts have labelled this legal right as the right to be born "with a sound mind and body" or "free from defects."

U.S. commentators have argued that when this right is combined with society's increased willingness to scrutinize prenatal conduct, the medical profession's growing view of the foetus as a patient, independent from the mother and with a developing standard of care that promotes prenatal testing, the right can be seen as expanding to cover parental and physician decision-making in the context of genetics.[221] Others have suggested that the emergence of the right to a sound mind and body may be driven by a desire to prevent human suffering. From the perspective of some proponents of such a right, it would operate to ensure that children do not suffer needlessly with a severe disability or with a life-threatening genetic disease.[222]

However, there are other commentators who have expressed deep concerns with the emerging right to be born with a sound mind and body. Widespread acceptance of such a right for the embryo or foetus would undoubtedly violate or infringe upon the woman's right to liberty and privacy, especially if the state attempted to impose mandatory genetic screening.

Both prenatal testing and PGD[223] require invasive surgical procedures into the woman's body; such mandatory screening would thus constitute state interference with the woman's liberty and bodily integrity. Furthermore, because the testing would be mandatory, it would remove the requirement for a woman's freely given consent, an essential requirement for medical treatment of any kind.

Many of the opponents of a right to be born with a sound mind and body can be found in the U.S. pro-life movement.[224] The legal right to be born with a sound mind and body is most often claimed by a child plaintiff in a tort action for wrongful life. Actions for wrongful life are viewed by pro-life groups as violating the sanctity of human life and encouraging physicians to perform abortions.[225]

One Canadian academic, Bernard Dickens, noted that the judicial treatment of wrongful life cases is surprisingly similar to that initially given to wrongful birth cases. He observed that the courts were initially reticent to recognize wrongful birth cases, using the same arguments that are used today by the judiciary to dismiss wrongful life cases. However, he noted that today courts are increasingly unwilling to say as a matter of law that life, even with the most severe and debilitating of impairments, is always preferable to non-existence.[226]

In his view, rhetoric about the sanctity of life and the symbolic or public policy goal the law must serve in the celebration of life ignores the harsh reality of life for many severely disabled persons. He suggested that this is especially true in the U.S. where meagre public health services fail to provide adequately for all of its citizens. He noted that, even in Canada, provincial health insurance plans operate on subrogation and the provinces are often anxious to recover additional care costs through plaintiff court actions.[227]

Furthermore, he observed that judicial resistance to claims for wrongful life reveal a "reactionary insistence" that human birth is always beneficial. In his view, the law could retain its integrity and potential to achieve social justice by recognizing claims for pain, suffering and financial costs that can be attributed to others' negligent acts.[228]

---

[220] Shepherd, *supra* note 215 at 3.
[221] *Ibid.* at 4.
[222] *Ibid.* at 8.
[223] In order for PGD to be carried out the embryos must exist outside the woman's body, i.e., *in vitro*. In order to fertilize the woman's eggs outside her body, they must be removed via an invasive procedure into her body.
[224] Dickens, *supra* note 187 at 80.
[225] *Ibid.* at 81.
[226] *Ibid.* at 90-1.
[227] *Ibid.* at 95.
[228] *Ibid.* at 107.

One way to do this would be to allow the child born with a preventable genetic disease to ground an action in tort for wrongful life.

Some U.S. academics have argued, however, that an individual fœtus has the right to be free from any genetic manipulation: a fœtus has the right to enter the world unaffected by their predecessors' genetic priorities and wishes.[229] They suggest that this right would flow from the right to security of the person guaranteed in international instruments, such as the UDHR and the ICCPR.[230]

The discourse of rights presumes that one has the ability to demand, exercise and enforce their rights. This is difficult if one is not yet a member of human society.[231] However, the issue of non-existence has not hampered the increase in preconception tort claims in the U.S. for injuries sustained prior to the child's conception and birth.

It has been suggested that because *in vitro* fertilization separates the embryo from the woman's womb, the *in vitro* embryo could be viewed as a separate and physically discrete unit possessing rights independent of the mother.[232] If that were the case, could one argue that the *in vitro* embryo possesses a human right to be born with a sound mind and body? Such a right might oblige others to conduct PGD and to select only those embryos for transfer that appear free of life-threatening or debilitating disease or to provide the embryo with genetic or other therapies to ensure its development into a healthy human being.

Presumably, such a right would not conflict with the mother's right since the *in vitro* embryo is outside her body. Legal counsel could always be assigned to represent the *in vitro* embryo's interests, as is the case today with children who sue for prenatal or preconception injuries, or for wrongful life.

3.7.2.4 The Law in Canada

The law in Canada has not recognized the rights of a fœtus or embryo until they are born alive, although recent cases, such as *Petkovic (Litigation Guardian of) v. Olupona*[233] and *McDonald-Wright (Litigation Guardian of) v. O'Herlihy*,[234] indicate that this approach may be changing. In *Winnipeg, supra*, the court referred to the general principle that in Canadian law a fœtus is not recognized as a legal person capable of possessing rights. However, once the child is born alive, the law may acknowledge that the child existed prior to its birth for limited purposes, i.e., the court may look back and acknowledge prenatal existence. [235]

In 1972, the High Court of Ontario, in *Duval et al. v. Seguin et al.*[236] ("*Duval*"), recognized that a driver of a motor vehicle owed a duty of care to a fœtus which was actionable by the child as soon as it was born alive. In its decision, the Court traced the history of foetal legal rights, noting that for some purposes, such as property rights, the fœtus has long been recognized as having rights.[237]

The Court examined American case law and noted that until 25 years ago the weight of authority was against recovery for damages by the child for prenatal injuries. According to the Court, the most oft-cited reasons for denying the child such a right of recovery was the difficulty establishing causation, the likelihood of extravagant testimony and fraud, and the fear that it would open the litigation floodgates to speculation and abuse.[238] However, the Court noted that today the position is reversed.[239] For example, in *Sinkler v. Kneale*,[240] the Supreme Court of Pennsylvania held that a child could maintain an action for an injury received when it was a one-month-old fœtus.

In addition, the Ontario Court referred to *Montreal Tramways Co. v. Leveille*[241] ("*Montreal*"), a case decided in

---

[229] Munayyer, *supra* note 1 at 10 (Lexis Nexis); Hendricks & Nowak "Western European Case Study: The Impact of Technology on Human Rights. Global Case Studies 243 (C.G. Weeramantry ed., 1993) at 272; Recommendation 934 of the Council of Europe on Genetic Engineering. Eur. Parl. Ass., 22nd Sess., Doc. Nos. 4832-33 (1982) (acknowledging the right to inherit a genetic pattern that has not been artificially altered), reprinted in Rogers & de Bousingen *Bioethics in Europe* (1995) at 303.

[230] *Ibid.* (Munayyer) at 10.

[231] *Ibid.* at 11.

[232] Roberts, *supra* note 12 at 10 (Lexis Nexis).

[233] *Petkovic (Litigation Guardian of) v. Olupona*, [2002] O.J. No. 1269 (Ont. Superior Court of Justice) (QL).

[234] *McDonald-Wright (Litigation Guardian of) v. O'Herlihy*, [2005] O.J. No. 135 (Ont. Superior Court of Justice) (QL).

[235] See more discussion re *Winnipeg supra* note 92 at 19 and in Chapter 2 at 48.

[236] *Duval et al. v. Seguin et al.* [1972] 2 O.R. 686-703 (Ont. Court of Justice) (Lexis Nexis); affm'd (1974), 1 O.R. (2d) 482 (Ont. Court of Appeal).

[237] *Ibid.* at 7.

[238] *Ibid.* at 7-9.

[239] *Ibid.* at 8.

[240] *Sinkler v. Kneale* (1960), 164 A. 2d 93.

[241] *Montreal Tramways Co. v. Leveille*, [1933] S.C.R. 456.

1933 by the Supreme Court under the civil law of Quebec. In *Montreal*, the Court held the defendant liable for injuries received by the child *en ventre sa mere* or *in utero*.[242] Under the civil law, a fœtus was considered alive when to do so was for its benefit.[243]

Lamont J., speaking for a majority of the Ontario Court in *Duval*, noted that:

> ...no decided case (or at most only one) has been found in which the child's right of action for pre-natal injuries has been maintained. The paucity of decided cases is far from conclusive, and may be largely accounted for by the inevitable difficulty or impossibility of establishing the existence of a causal relation between the fault complained of and the injury to the child. With the advance in medical science, however, that which may have been an insuperable difficulty in the past may now be found susceptible of legal proof.[244]

It has been noted that *Duval* brought attention to the issue of liability and the unborn, and the expansionary trends of negligence law.[245] The courts have been resistant to claims for wrongful birth in which the mother claims damages for the unwanted birth of a healthy child.[246] When a child has been born with disabilities, the courts response has been mixed.[247]

The case of *Dobson (Litigation Guardian of) v. Dobson*[248] ("*Dobson*") established that a duty of care is not owed by a mother to her unborn child. A majority of the Supreme Court expressed concern that if such a duty was found in the case, it might be expanded beyond the operation of motor vehicles and lead to judicial scrutiny and assessment of all maternal activities that might pose a risk to the fœtus, such as continuing in the work force and careless performance of household activities.[249] The minority in *Dobson* would have recognized a duty in the present case, i.e., a duty to drive safely, because such a duty is already owed to third parties.[250]

The Canadian courts have traditionally resisted recognizing a cause of action for wrongful life. For example, in *Lacroix (Guardian of) v. Dominique*[251] ("*Lacroix*"), the Manitoba Court of Appeal was asked to decide whether the trial judge had correctly dismissed the child's claim for wrongful life. The Court followed the reasons in *McKay, supra*, and held that such a cause of action could not be maintained in Canada.[252] In 2001, the Supreme Court denied leave to appeal.

Petkovic (Litigation guardian of) v. Olupona[253] ("*Petkovic*") suggests a slight crack in the courts resistance. The Ontario Superior Court of Justice was asked to strike out a claim for wrongful life by a minor plaintiff on the ground that it did not disclose a reasonable cause of action. The defendants relied in part on the fact that the Supreme Court denied leave to appeal in *Lacroix*, arguing that it must now be considered settled law in Canada that an action for wrongful life cannot be maintained.[254]

The Court responded by stating:

> The fact that the Supreme Court refused leave in Lacroix is not, in my respectful opinion, dispositive of the issue on a national basis even though subsumed in the application is an issue of great and universal concern. It does not follow that the court accepted the decision of the Manitoba Court of Appeal without question...a denial of leave can occur for any number of reasons...[T]he decision of the Manitoba Court of Appeal in rejecting the wrongful life claim is rooted, without analysis, in the decision of the English Court of Appeal in *McKay* v. *Essex Area Health Authority*... Arguably, when that decision is subjected to careful scrutiny, it in turn appears to be reflective of the then-English public policy and the prevailing statutory regime in respect of the protection of viable foetii.

---

[242] *Duval, supra* note 233 at 7 (Lexis Nexis).

[243] *Ibid.* at 7.

[244] *Ibid.* at 9.

[245] Osborne, *supra* note 190 at 1 (QL).

[246] Jocelyn Downie, Timothy Caulfield and Colleen Flood, *Canadian Health Law and Policy* (Markham, Ontario: Butterworths, 2002) at 361.

[247] *Ibid.*

[248] *Dobson (Litigation Guardian of) v. Dobson*, [1999] 2 S.C.R. at 753. Online: http://www.lexum.umontreal.ca.

[249] *Ibid.* at 13.

[250] *Ibid.* at 25.

[251] *Lacroix (Guardian of) v. Dominique*, 2001, Man. Court of Appeal. Online: http://www.Canlii.org/mb/cas/mbca/2001mbca122.html; leave to appeal to the Supreme Court of Canada denied [2001] S.C.C.A. No. 477.

[252] *Ibid.* at 7.

[253] *Petkovic, supra*, note 230 (QL).

[254] *Ibid.* at 2.

> [...]
>
> Furthermore, I am not persuaded that the "sanctity of life" notion that appears to underpin in part the decision of at least one of the members of the court in *McKay*, remains as sacrosanct today as apparently it was at the time of that decision...In my opinion, the issue of the existence of a cause of action for wrongful life is not clear, obvious and beyond doubt, particularly as it is presently pled.[255]

The court dismissed the defendants' motion to strike the plaintiff child's claim and allowed it to go forward.[256] On appeal, the Divisional Court of Ontario[257] referred to the decision of Sharpe J. in two unreported 1997 wrongful life cases, where he stated:

> In my view, the appropriate order...is to permit the 'wrongful life' claim to proceed to trial. This is an evolving area of law. The issue has not been considered in depth by Canadian courts. It is only recently that the parents 'wrongful birth' claim was [sic] been recognized by a Canadian court...More generally, the legal regime relating to abortion has undergone significant change resulting in an expanded scope for parental choice.[258]

The Divisional Court held that the lower court had correctly decided the issue by allowing the action to proceed to trial. Epstein J. noted:

> It [should] be for the trial judge, in the context of a complete record, to determine whether the plaintiff should have a remedy. This is how the progress of the common law is marked in cases of first impression, where the court has created a new cause of action where none had been recognized before.
>
> A few years ago wrongful life was not considered to be a cause of action and now it is. Plaintiffs' counsel argues that the law in this area is clearly in a state of flux...I am of the view that in this complex area, a trial record may be of assistance to the appellate court.[259]

The Court dismissed the defendants' motion for leave to appeal the lower court's decision and allowed the child's claim to go forward. In doing so, the Court stated "...there is no reason to doubt the correctness of the principles used by the learned motions judge in the exercise of his discretion."[260]

In 2005, the Ontario courts are once again facing a claim by a child for wrongful life. *McDonald-Wright (Litigation Guardian of) v. O'Herlihy*[261] is in many respects similar to *Petkovic, supra.* The Ontario Superior Court of Justice was asked to rule on a motion striking a claim by the injured child, Beau McDonald-Wright, against the defendants for wrongful life.[262] Justice Lax stated that a tort claim for wrongful life is a matter of law that has not been fully settled in either Ontario or Canada, and thus she held that "[i]t should proceed to trial."[263] In reaching her decision, she relied in part on Justice Wilson's comments in *Hunt v. Carey*:

> The fact that a pleading reveals "an arguable, difficult or important point of law" cannot justify striking out part of the statement of claim. Indeed, I would go so far as to suggest that where a statement of claim reveals a difficult and important point of law, it may well be critical that the action be allowed to proceed. Only in this way can we ever be sure that the common law in general, and the law of torts in particular, will continue to evolve to meet the legal challenges that arise in our modern industrial society.[264]

The significance of allowing a cause of action for wrongful life in Canada would lie in the fact that, as was the case in the U.S., at some point the courts might have to struggle with the question of whether a child has a legal right to be born with a sound mind and body.

---

[255] *Ibid.*

[256] *Ibid.* at 3.

[257] *Petkovic v. Olupona*, [2002] O.J. No. 3411 (Ont. Ct. of Justice, Divisional Court) (QL).

[258] *Ibid.* at 2.

[259] *Ibid.* at 4.

[260] *Ibid.* at 4. There are no further reports of *Petkovic*. It may be that the case was settled out of court and is unreported.

[261] *McDonald-Wright, supra* note 231(QL).

[262] *Ibid.* at para. 1.

[263] *Ibid.* at para. 16.

[264] *Hunt v. Carey Canada Inc.*, [1990] 2 S.C.R. 599 at para. 49.

3.7.2.5 Discussion

The following discussion addresses a controversial area and it is restricted to the evolving situation in the U.S. It examines whether the emerging legal right to be born with a sound mind and body, currently grounded in tort law, could evolve into a human right.

In the past, there were no scientific or medical procedures available to diagnose a genetic disease in an *in utero* embryo, fœtus or an *in vitro* embryo. Today, if physicians or clinics fail to advise parents at risk about genetic testing, such as PGD or amniocentesis, children born with a life-threatening genetic disease may claim damages in certain U.S. states based on wrongful life and a legal right to be born with a sound mind and body. In other states, the child's claim for wrongful life would be dismissed. However, the parents would likely still be able to sue the physician for a prenatal tort for damages occurring before or after birth, but after the child's conception,[265] depending on the facts of the case.

It is possible to foresee that as rapid advances in biotechnology occur, society and the courts may have cause to rethink more traditional human rights concepts and perhaps create new ones.

One solution might be to broaden the child's right to be born with a sound mind and body to apply outside the civil tort law context. Could such a right be grounded in constitutionally protected guarantees to liberty or security of the person? Could the right be narrowed so that it applied to only those *in vitro* embryos selected for reproduction purposes? The right would only exist during the time between the creation of the *in vitro* embryo and the embryo's transfer into the woman. Once the *in vitro* embryo is transferred, the rights of the woman and the *in utero* embryo would have to be balanced (this approach would be similar to that adopted by Louisiana, under its *Code*, where the *in vitro* embryo only has legal rights prior to transfer).

The recent right to procreational autonomy was derived from the constitutional guarantees to liberty and privacy, which originated in the First, Fourth and Fifth Amendments to the *U.S. Constitution*. Any rights secured under the guarantee to privacy are considered fundamental by the courts because they are located within areas of a personal nature where unwarranted governmental intrusion is deemed improper. Fundamental rights are granted the highest protection under the law.

The U.S. has signed but not ratified the U.N. *Convention on the Rights of the Child* ("CRC"). The rights provided in the CRC could be referred to the courts for their interpretive value with respect to the *U.S. Constitution* and domestic legislation. Article 24(1) provides that State Parties recognize the right of the child to the enjoyment of the highest attainable standard of health. It could be relied on to support an argument that children have a right to be born in the best possible state of health. This right could include and protect parental access to genetic testing, such as PGD, without state interference, to ensure as far as possible that the child would be born without a particular genetic disease. It could be argued that the state should not deny access to readily available technology to assist the future child in the enjoyment and attainment of the highest standard of health. However, since these international instruments speak only of children, it is questionable whether they would be interpreted to apply to a future child existing as an *in vitro* embryo.

Such a right would be a negative right vis-à-vis the state. The right would impose a duty on the state not to interfere with the parent's access to PGD to ensure that the *in vitro* embryo selected would, as a child, have the potential to enjoy the highest possible standard of health.

Although the state duty would be to a future person, this approach accords with that already taken by the court in preconception tort claims, where the physician has a duty of care, when treating the woman, to any future children as well. The state's duty would be to the future child, existing as an *in vitro* embryo, while the child's right would only crystallize once it is born alive. This approach would also be similar to that taken by the court in prenatal tort claims. The court recognizes the child's existence prior to its birth for the specific and limited purpose of allowing tort actions for damages. In addition, the courts generally inquire whether such an approach is in the child's best interest.

---

[265] Collins, *supra* note 184.

Once the child is born alive, the courts could be asked to look back to the time when the child was an *in vitro* embryo for the limited purpose of asserting a claim against the state for depriving his or her parents of access to information necessary to allow optimum health. This approach would accord with the long-standing common law rule of only granting rights to an fœtus once born alive. The child's right would be a negative right, meaning that the child has a right to be born of sound mind and body, free from state interference.

Assuming the right to be born with a sound mind and body was grounded in one or more of the Amendments to the *U.S. Constitution*, the state could still limit the right. It could infringe on the right, but only where the state has what the American courts consider a "compelling reason."

3.7.2.6 Conclusion

Despite evidence from the U.S. that the right to be born with a sound mind and body is an emerging legal right, it has only been recognized in three U.S. states and only in the context of a civil action for wrongful life. To date, the courts in Canada have been unwilling to recognize actions for wrongful life, although there is some evidence in lower court decisions that this may change. In addition, the courts in Canada have not yet been asked to decide on the existence of a legal right to be born of sound mind and body.

In the UK, recent legislative amendments appear to have opened the door to claims for wrongful life, at least in the context of AHR procedures. As technology advances and testing for genetic anomalies becomes more accessible and less intrusive, the courts might begin to recognize claims based on a right to be born with a sound mind and body. Over time, such a right might evolve into a fundamental right or norm. It would become more difficult for the state to prohibit access to tests, such as PGD, as well as gene therapies developed to eradicate genetic disease in the *in vitro* embryo. As a negative right, the child would be able to challenge the state prohibition as violating a fundamental right to be born in optimal health — of a sound mind and body — to enjoy the highest attainable standard of health.

Whether such a right would evolve into a *Charter*-protected right in Canada, is highly speculative. It remains extremely difficult to attain a consensus viewpoint within society about the moral and legal status of an *in vitro* embryo. The same difficulty exists at the international level and would likely hamper any attempt to fashion such an international norm or right for the *in vitro* embryo.

In addition, any explicit right to screen for genetic disease would have to be balanced against the reproductive autonomy rights of the woman. For now, the issue is largely confined to the U.S. and unlikely to arise in other parts of the world unless and until access to AHR technologies, including PGD and genetic therapy, becomes relatively easy, somewhat affordable and viewed as a culturally acceptable intervention.

3.8 Conclusion

Although foetal rights have been dealt with by the courts in the context of civil litigation and to some extent in jurisprudence regarding abortion, the legal rights of an *in vitro* embryo, existing as it does outside the body of a woman, have not been decided by the courts. Advances in AHR technology, especially pre-conception and *in vitro* genetic diagnosis, may force the court to examine this issue sometime soon. The current lack of jurisprudence represents a gap in the existing human rights framework.

A right to reproductive autonomy, although not particularly clear or settled in the international arena, has been addressed to some extent by the courts in Canada. The right to liberty, enshrined in section 7 of the *Charter*, contains a right to make fundamental personal decisions without interference from the state (unless the interference is found to be in accordance with the principles of fundamental justice).

The courts have held that women in Canada have a degree of autonomy flowing from the liberty interest in section 7 to make personal decisions regarding reproduction. In particular, women have an unrestricted right to abort in the early stages of the pregnancy. This right to reproductive autonomy would most likely be found to protect a woman's decision to use AHR technologies. Furthermore, the woman's right to reproductive autonomy would arguably include the right not to be deprived of "necessary" medical information, about her *in vitro* embryos in order to make a decision regarding reproduction.

Now that certain provisions of the AHR Act have been proclaimed in force, the *Charter* will apply to some of the activities discussed in this chapter. It is likely that disputes will arise between individuals and the state with respect to some of the prohibited activities. The courts in Canada will, for the first time, be faced with deciding these issues and will no doubt be referred to rights and principles set out in international instruments. The challenge for the courts will be to decide these issues in a forward-looking manner, taking into account broader societal interests, as well as individual rights. The pluralistic nature of Canada, in which communities and individuals hold differing moral and ethical views, as well as the unknown and uncharted path represented by these new technologies, will combine to make this task extremely challenging.

Government of Canada Gouvernement du Canada

A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 4

A Right to Research

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 4

Table of Contents

4.1 Introduction 4–1

4.2 Research Using an *In Vitro* Embryo 4–1

4.3 Background 4–2

4.4 Issues 4–5

4.5 Issue 1: Is There a Human Right to Undertake Scientific Inquiry? 4–5

- 4.5.1 International and Regional Instruments 4–6
- 4.5.2 The Law in Other Jurisdictions 4–8
- 4.5.3 The Law in Canada 4–11
- 4.5.4 Academic Literature and Other Commentary 4–16
- 4.5.5 Discussion 4–22
- 4.5.6 Conclusion 4–26

4.6 Issue 2: The Right to Benefit from Scientific Progress 4–26

- 4.6.1 International and Regional Instruments 4–26
- 4.6.2 The Law in Other Jurisdictions 4–26
- 4.6.3 Academic Literature and Commentary 4–26
- 4.6.4 The Law in Canada 4–27
- 4.6.5 Discussion 4–28
- 4.6.6 Conclusion 4–29

4.7 Issue 3: The *In Vitro* Embryo 4–30

- 4.7.1 The Law in Other Jurisdictions 4–30
- 4.7.2 Academic Commentary 4–31
- 4.7.3 Discussion 4–33
- 4.7.4 Conclusion 4–35

4.8 Conclusion 4–35

Chapter 4

A Right to Research

Judy Hunter

4.1 Introduction

Advances in biotechnology are expanding the frontiers of knowledge through scientific research and discoveries in many fields, such as health and the environment. The impact of scientific advances in this century is predicted to be greater than the impact telecommunications and computers in the last. However, because biotechnology research often involves the manipulation of living things, it can generate controversy, as well as excitement.[1]

Should scientists interfere with nature and alter life? Should animals and humans be cloned? Should plants be genetically modified? Should human embryos be created or used for research purposes? All of these questions raise moral, ethical and legal concerns. It is difficult to reach a consensus in society as to whether these activities should be undertaken since individuals and groups often hold strong and diametrically opposed views.

Since 1999, the Canadian Biotechnology Secretariat ("CBS") has tracked public opinion regarding biotechnology and the public policy that surrounds it. The CBS has consistently found in its opinion research that Canadians are open-minded and supportive of the benefits associated with biotechnology, especially those related to medical discovery, an improved quality of life, and new jobs. Two-thirds of those polled consider themselves supportive of Canada's focus on biotechnology, as long as any potential risks are carefully managed and mitigated.[2]

This chapter focuses on the human rights issues that may arise with respect to scientific research. Research using embryonic stem cells derived from a human *in vitro* embryo is used as an example throughout the chapter. This example was chosen because there is a general awareness of the scientific advances and promises respecting this area of research, and there is a plethora of academic commentary. Furthermore, the derivation and use of embryonic stem cells from human embryos generates widely differing moral, ethical and legal perspectives.[3]

4.2 Research Using an *In Vitro* Embryo

The possibility of using a human embryo for research purposes became a reality in the late 1970s and the early 1980s with the growing success of *in vitro* fertilization. Medical and scientific researchers began to use *in vitro* embryos to derive embryonic stem cells in the hopes of using them to invent cures for debilitating and life-threatening disease in humans.[4] The use of human *in vitro* embryos in such research is troubling to many individuals since the derivation of stem cells from the embryo results in its destruction.

---

[1] Government of Canada, *Biotechnology Transforming Society: Creating an Innovative Economy and a Higher Quality of Life Report on Biotechnology 1998-2003* at 2.

[2] *Ibid.* at 5.

[3] Françoise Baylis, "Betwixt and Between Human Stem Cell Guidelines and Legislation" (2002) 11 Health L. Rev. No. 1, 44-50 at 2 (QL).

[4] Denise Stevens, "Embryonic Stem Cell Research: Will President Bush's Limitation on Federal Funding Put the United States at a Disadvantage? A Comparison Between U.S. and International Law" (2003) 25 Hous. J. Int'l L. 623 at 3 (Lexis Nexis). For example, the application of biotechnology to reproductive materials, such as the *in vitro* embryo, may one day allow scientists to grow replacement tissues or organs for transplant that would not be rejected by the recipient. This technology could be used to solve the current shortages of compatible tissues and organs for transplant.

In some jurisdictions, researchers are able to create *in vitro* embryos solely for research purposes as a source of embryonic stem cells, either through *in vitro* fertilization, somatic cell nuclear transfer[5] (therapeutic cloning), embryo splitting, or parthenogenesis.[6] In these jurisdictions, researchers have a continuous supply of *in vitro* embryos and embryonic stem cells for their research activities. In other jurisdictions, that only permit the creation of *in vitro* embryos for reproductive purposes, researchers must rely on individuals or couples to donate their excess or supernumerary embryos to research, i.e., those *in vitro* embryos no longer required for reproductive purposes.

4.3 Background

The science

There are five possible sources of embryonic stem cells: (1) an *in vitro* embryo created for reproductive purposes and now considered supernumerary, (2) an *in vitro* embryo created specifically for research by the fertilization of an egg with sperm, (3) an *in vitro* embryo created by therapeutic cloning, (4) an *in vitro* embryo created through embryo splitting, and (5) an *in vitro* embryo created through parthenogenesis.

Stem cells

Approximately five days after fertilization, when the *in vitro* embryo becomes a blastocyst and has more than 100 cells, stem cells can be isolated from the inner cell mass and cultured in the lab to form embryonic stem cell lines. These cells are unique because they have the capacity to self-renew and to differentiate into other tissues in the body.[7] The isolation and removal of these cells result in the destruction of the embryo.[8]

Embryonic stem cell lines can grow and divide indefinitely. They can also be frozen in small batches for future research and distributed to other scientists,[9] and they can be stimulated to develop into any other cell type, such as nerve, blood, brain or muscle cells. Many researchers regard these microscopic cells as holding the key to future cures and therapies. They could potentially be used to replace damaged or diseased tissues or organs.[10] Many diseases, such as Parkinson's disease and juvenile-onset diabetes, result from the loss or dysfunction of certain cell types. The replacement of those damaged cells could offer an effective treatment or even a cure.[11] Furthermore, stem cells could be cultured in the laboratory to develop into specific tissue or organs for transplant. It is in this area of research that embryonic stem cells are thought to currently offer the most hope.

When stem cells divide, they either remain stem cells or become other more specialized cells. Theoretically, they could divide indefinitely to replenish other cells.[12] Most specialized cells in the human body do not divide but rather are replaced or replenished from populations of stem cells already present in most of the tissues of the body.[13] These older stem cells are found in the tissues and organs of the human body and are referred to as "adult stem cells."[14]

These stem cells are most prolific in those tissues and organs that are constantly undergoing renewal, such as in bone marrow, in the skin, and in the lining of the small intestine.[15] The cells in these tissues are constantly dying and being replaced by cells from a subpopulation of dividing stem cells that generate replacements for the relatively short-lived, terminally differentiated cells.[16]

---

[5] "Somatic cell nuclear transfer" is a process whereby the nucleus of a human egg is removed and replaced with the nucleus from a donor cell. The egg is artificially stimulated and begins to develop as an *in vitro* embryo. (The President's Council on Bioethics, "Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) at 132.) Online: http://www.bioethics.gov/reports/cloningreport/fullreport.print.html.

[6] "Parthenogenesis" is a form of nonsexual reproduction in which eggs are subjected to electrical shock or chemical treatment in order to initiate cell division and embryonic development (The President's Council on Bioethics, "Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) at 132. Online: http://www.bioethics.gov/reports/cloningreport/fullreport.print.html.

[7] These cells are considered "pluripotent," meaning that they are able to give rise to most types of tissue but not capable of bringing a functioning organism into existence. They can be kept alive in an artificial medium and will proliferate more or less indefinitely. *Ibid.* (D. Stevens) at 4.

[8] *Supra* note 4 at 2 (Lexis News).

[9] Dr. Ali Asangla, McGill University Montreal (e-mail correspondence April 6, 2004); Stem Cell Network, Research Overview. Online: http://www.stemcellnetwork.ca/research/overview.php?lang Accessed April 2004. Opinion of the European Group on Ethics in Science and New Technologies to the European Commission, No. 15, *Ethical Aspects of Human Stem Cell Research and Use* (November 14, 2000) at 4.

[10] The U.S. National Bioethics Advisory Commission (established by executive order of President Bill Clinton on October 3, 1995) *Ethical Issues in Human Stem Cell Research*, Vol. I (Rockville, Maryland, September 1999) at 8.

[11] *Ibid.* at 20.

[12] For basic information about stem cells see: http://stemcells.nih.gov/stemcell/whatAreStemCells.asp#1

[13] Meredith Mariani "Stem Cell Legislation: An International and Comparative Discussion" (2002) 28 J. Legis. 379 at 2-3 (Lexis News).

[14] *Supra* note 4 at 2 (Lexis News).

Adult stem cells have been found to have less capacity to differentiate into other cell types, and their differentiation patterns are less predictable and less well controlled, than embryonic stem cells. To date, scientists have not been able to successfully grow large numbers of adult stem cells in culture: these stem cells are difficult to isolate and maintain.[17] In addition, they do not possess the same degree of "elasticity" as embryonic stem cells because they serve the purpose of regeneration and repair only in specific tissues and organs.[18]

Recent studies have shown that adult stem cells may have more therapeutic potential than originally thought.[19] However, most scientists believe that research should continue on both types of stem cells.[20]

Many scientists still contend that embryonic stem cells are the "most fundamental and extraordinary of the stem cells."[21] They have been termed the "essence of the embryo" because they are the biological building blocks that serve as the common ancestry of all 210 different kinds of tissue in the human body.[22]

Sources of Stem Cells

Supernumerary in vitro *embryos*

When an individual or couple undergo *in vitro* fertilization for reproductive purposes, many more *in vitro* embryos are usually created than can be transferred in a single treatment cycle. The remainder are usually frozen for their future reproductive use. Once the individual or couple complete their family, there are often frozen *in vitro* embryos remaining in storage. Their disposition options are limited to donating for the reproductive use of others, donating to research or allowing them to perish.

Those supernumerary *in vitro* embryos that are donated to research can become a source of embryonic stem cells for the scientist.

Embryos created for research

Along with the ability to fertilize a human egg with human sperm outside a woman's body for reproductive purposes, came the possibility use such an *in vitro* embryo for research purposes.

Therapeutic cloning

In 1997, Ian Wilmut at the Roslin Institute in Edinburgh, Scotland, successfully cloned a ewe. Wilmut used somatic nuclear cell transfer to create "Dolly," the cloned ewe.

In February 2004, scientists in South Korea successfully created 30 therapeutically cloned *in vitro* embryos, grew them to the blastocyst stage (5-6 days) and derived a pluripotent stem cell line from them.[23] Scientists hope to use the stem cells to repair damaged tissue and to treat a variety of diseases.[24] This was the first successful cloning of human embryos and their successful growth to the stage at which embryonic stem cells could be derived.[25]

Therapeutic cloning, sometimes referred to as somatic cell nuclear transfer, uses the same process as reproductive cloning. It involves the isolation of a somatic (i.e., body) cell from a donor, such as a skin cell, and the removal of the cell's nucleus. The nucleus is then inserted into a donated human egg whose nucleus has been removed.[26] The egg is then stimulated electrically or chemically to begin cell division and development into an embryo.[27] The nucleus of the resulting embryo now contains only the skin cell donor's genetic material.[28]

---

[15] *Supra* note 10 at 12.

[16] *Ibid.*

[17] *Supra* note 4 at 4; Andrew Pollack, *The Stem Cell Debate: Scientists Seek Ways to Rebuild the Body, Bypassing the Embryos* (N.Y. Times, Dec. 18, 2001) at F6; Meridith Mariani "Stem Cell Legislation: An International and Comparative Discussion" (2002) 28 J. Legis. 379 at 4 (Lexis Nexis).

[18] *Supra* note 13 at 4 (Lexis Nexis).

[19] *Ibid.*

[20] *Ibid.*

[21] *Supra* note 10 at 7 (Lexis Nexis).

[22] *Supra* note 4 at 2 (Lexis Nexis).

[23] The President's Council on Bioethics, "Reproduction & Responsibility: The Regulation of New Biotechnologies" (Pre-Publication Version) (Washington, D.C., March 2004) at 127-8.

[24] Canadian Broadcasting Services, "Scientists clone human embryos" (February 12, 2004). Online: http://www.cbc.ca/dgi-bin/templates/print.cgi?2004/02/12/clone04-212.

[25] *Supra* note 23 at 128.

[26] *Supra* note 4 at 2 (Lexis Nexis).

[27] James J. McCartney, "Embryonic Stem Cell Research and Respect for Human Life: Philosophical and Legal Reflections" (2002) 65 Alb. L. Rev. 597 at 3 (Lexis Nexis).

[28] *Supra* note 4 at 2 (Lexis Nexis).

One might conclude that the resulting embryo is a clone or replica of the skin-cell donor. However, this is questionable since the plasma of the donated egg contains also contains DNA (from the egg donor) in its mitochondria which is different from the DNA in the embryo's nucleus (donated by the skin cell donor), and thus it is unlikely that the cloned embryo is an exact replica of the skin cell donor.

The scientific theory underlying this process is that stem cells removed from the therapeutically cloned *in vitro* embryo would be compatible with the skin cell donor, so that any cells, tissues or organs created from the stem cells could be transplanted into the donor without fear of rejection by the body. The customized cells, tissues or organs would contain the skin cell donor's own genes, and thus would not be attacked and destroyed by his or her immune system.[29]

It is important to note, however, that there is no consensus on the issue of rejection or that somatic cell nuclear transfer is the most effective process to address this problem. Even if there is an immune rejection problem associated with donated stem cells, there may be other solutions to that problem that do not require the use of therapeutically cloned *in vitro* embryos.[30]

Some scientists believe that as research proceeds, it may be possible to bank stem cell lines derived from donated *in vitro* embryos, or foetal tissue with defined major histocompatible complex backgrounds.[31] Stem cell banks could be developed and stocked with each type of stem cell, similar to the system of typing and storing blood for transfusion, to provide those in needs of stem cell therapy with compatible cells. Other scientists believe it may be possible to develop universal donor stem cell lines by genetically manipulating the stem cells to reduce or actively combat immune rejection.[32]

Embryo splitting

In the early 1990s, two scientists successfully used embryo-splitting to produce a few genetically identical organisms from the blastomeres of non-viable human *in vitro* embryos. The experiment was conducted for purely scientific objectives and without any intention of using the embryos for reproductive purposes.[33]

In 1999, scientists successfully created, through embryo splitting, the first nonhuman primate, a rhesus monkey named Tetra. An eight-cell *in vitro* embryo was split to produce a set of identical quadruplet embryos, each consisting of two blastomeres. Two of the blastomeres were inserted into empty zona pellucidas,[34] creating one set of quadruplets. A pair of the quadruplet embryos were transferred into two fertile surrogate monkeys and both became pregnant. Tetra, born at 157 days after an uneventful pregnancy, resulted from one of the transferred embryos.[35]

Scientists could obtain a number of human *in vitro* embryos for research purposes by removing several blastomeres from a single donated *in vitro* embryo at the 4 to 16 cell stage of development.[36] Each blastomere would theoretically be capable of developing into a genetically identical *in vitro* embryo in the laboratory.

Parthenogenesis

Scientists could create *in vitro* embryos through parthenogenesis. The term "parthenogenesis" is derived from the Greek words for "virgin birth." This process subjects a human egg to electrical shock or chemical stimulation that causes it to begin cell division and embryonic development, despite the absence of fertilization.[37] In modern biology, parthenogenesis refers to a form of reproduction in which an egg develops into a new individual without having been fertilized.[38] This form of reproduction occurs naturally among some insect species, such as bees and ants.

---

[29] *Ibid.* at 2-3 (Lexis Nexis).

[30] Françoise Baylis, Testimony before the Senate Standing Committee on Social Affairs, Science and Technology, February 26, 2004.

[31] Statement of James Thomson, December 2, 1998, s. Hrg 105-939. Hearings before a subcommittee of the Committee on Appropriations United States Senate. One Hundred fifth congress. The term "histocompatible" means that the tissues of different individuals would be compatible (Concise Oxford Dictionary, 10th Ed.).

[32] Statement of John Gearhart December 2, 1998, s. Hrg 105-939. Hearings before a subcommittee of the Committee on Appropriations United States Senate. One Hundred fifth congress.

[33] Sonia Le Bris and Marie Hirtle, "Ethical and Legal Aspects of Human Cloning Comparative Approaches" in Bartha Maria Knoppers, ed., *Socio-Ethical Issues in Human Genetics* (Cowansville: Les Éditions Yvon Blais Inc., 1998) at 290.

[34] The "zona pellucida" is the thick transparent membrane surrounding the mammalian ovum before fertilization. (The Concise Oxford Dictionary, 10th Edition.)

[35] A.W. s. Chan, et al., "Clonal Propagation of Primate Offspring by Embryo Splitting" (2000) 287 Science at 317.

[36] *Supra* note 33 at 290.

[37] The President's Council on Bioethics, "Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) at 132. Online: http://www.bioethics.gov/report/cloningreport/fullreport-pring.html.

In vitro embryos created through parthenogenesis would be derived from an unfertilized human egg. These embryos have only the genetic material of the female and thus are unlikely to develop into an *in vitro* embryo that has the potential for human life.

In 2002, American researchers from Wake Forest University School of Medicine, the Mayo Clinic and Advanced Cell Technology Inc. reported that they had developed a large variety of specialized cells, including heart and brain cells, from embryonic monkey stem cells obtained from an *in vitro* embryo created through parthenogenesis. Dr. Varna, one of the researchers, noted that "parthenogenesis offers an important new therapeutic strategy for a host of medical conditions." [39]

4.4 Issues

This chapter discusses three issues that arise with respect to scientific research. First, do researchers have a human right to undertake research or scientific inquiry? Second, do individuals have a right to enjoy the benefits and applications of scientific progress? Finally, does the purpose or method of creating a human *in vitro* embryo alter its moral status?

The discussion under each issue is organized under the following headings: (1) relevant international and regional instruments, (2) the law in other jurisdictions, (3) the law in Canada, (4) a discussion, and (5) a conclusion.

4.5 Issue 1: Is There a Human Right to Undertake Scientific Inquiry?

In order to undertake research to derive and study embryonic stem cells, scientists must have access to *in vitro* embryos. The derivation of embryonic stem cells from a human *in vitro* embryo results in its destruction. For those individuals and jurisdictions that assign the *in vitro* embryo the status of a human being with legal rights, its use and destruction for research could not be justified. Other individuals and jurisdictions have differing views of the *in vitro* embryo. It is often considered as either equivalent to other human tissue or as *sui generis* and, although deserving of respect, a proper subject of medical research.[40]

For those individuals and jurisdictions in the latter group, research using *in vitro* embryos may be acceptable as long as certain conditions are met. For example, in the United Kingdom ("U.K."), research on *in vitro* embryos is permitted, but only with a licence from the Human Fertilisation and Embryology Authority ("HFE Authority") and is restricted to the first fourteen days following fertilization.[41] The fourteenth day was chosen as the outer research limit in the U.K.'s 1985 *Warnock Report*[42] since it is the point in development just prior to the appearance of the primitive streak (the beginnings of a central nervous system) and the development of the three germ layers in the embryo.[43]

For many people, these physiological developments signal that the embryo is now a "unique individual" because it can no longer twin.[44] Prior to this point, the embryo can cleave naturally or artificially to produce identical siblings. For some individuals, up until this point, the embryo cannot be considered a "human individual" because the possibility still exists that the embryo could develop into more than one individual of the human species.[45]

For others, the proposed moral dividing line set by the fourteenth day limit is purely arbitrary. However, this limit or "quasi-break" in the ontogeny of a human being has come to be regarded as the legitimate demarcation point in other countries, including Canada.[46]

---

[38] Sean Henahan, "Asexual Stem Cell Production" Access Excellence Science Updates (02/05/02) Online: http://www.accessexcellence.org/WN/SU/SU102001/parthenogenesis.html. Accessed April 7, 2004.

[39] Advanced Cell Technology, "Researchers Develop Primate Stem Cells Without Creating Viable Embryos" (January 31, 2002). Online: http://www.advancedcell.com/2002-01-31.htm. Accessed April 7, 2004.

[40] See Chapter 2 for a more in-depth discussion of the status of the embryo.

[41] Section 3(3)(a) of the *Human Embryology and Fertilisation Act 1990*, (c.37).

[42] *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (London: Her Majesty's Stationery Office, 1984) (hereinafter referred to as the *Warnock Report*).

[43] M. Warnock, *A Question of Life: The Warnock Report on Human Fertilisation and Embryology* (Oxford: Basil Blackwell, 1985).

[44] John A. Balint, "Ethical Issues in Stem Cell Research" (2002) 65 Alb. L. Rev. 729 at 2 (Lexis Nexis).

[45] *Supra* note 29 at 4 to 5 (Lexis Nexis).

[46] Matthew Herder, "The UK Model: Setting the Standard for Embryonic Stem Cell Research?" (2002) 10 Health L. Rev. No. 2, 14–24, at 1 (Lexis Nexis).

In many jurisdictions, supernumerary *in vitro* embryos may be donated for research purposes, including the extraction of embryonic stem cells. However, some scientists believe that unless they can therapeutically clone an *in vitro* embryo as a source of stem cells that genetically match the donor, essential research on certain medical therapies and cures would be precluded.

4.5.1 International and Regional Instruments

The rights set out in the UDHR[47] informed the ICESCR[48] and the ICCPR.[49] Article 19 of the ICCPR states:

> 1. Everyone shall have the right to hold opinions without interference.
>
> 2. Everyone shall have the right to *freedom of expression*; this right shall include freedom to *seek, receive and impart information and ideas of all kinds*, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of choice.
>
> 3. The exercise of the rights provided for in paragraph 2 of this article carries with it special duties and responsibilities. It may therefore be subject to certain restrictions, but these shall only be such as are produced by law and are necessary:
>
>   a. For respect of the rights or reputations of others;
>
>   b. For the protection of national security or of *public order* (ordre public), or of *public health or morals*. [emphasis added]

The Human Rights Committee ("HRC") in General Comment 10 notes that paragraph 2 of article 19 provides two different but related rights, i.e., the right to disseminate information and ideas of all kinds and the right to seek and receive ideas and information of all kinds, regardless of the forum or the type of medium.[50]

General Comment 10 further notes that paragraph 3 of article 19 provides that certain restrictions can be imposed on the right to freedom of expression. State-imposed restrictions must be provided by law and must fulfil one of the purposes set out in paragraph 3, i.e., to protect the rights or reputations of others, and/or to protect national security, public order, public health or morals.[51]

The ICESCR provides in article 15(3):

> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for *scientific research* and creative activity. [emphasis added]

As noted in Chapter 1, Canada is a party to the ICCPR and the ICESCR.

UNESCO's *Universal Declaration on the Human Genome and Human Rights*[52] sets out the following principles in articles 11 and 12:

> Article 11
>
> Practices contrary to human dignity, such as *reproductive* cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected. [emphasis added]

---

[47] *Universal Declaration of Human Rights*, GA Res. 217 (III) GOAR, 3rd Sess., Supp. No. 13, UN Doc. A/810 (1948), [hereinafter UDHR].

[48] *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976), [hereinafter ICESCR].

[49] *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171 (entered into force 23 March 1976), [hereinafter ICCPR].

[50] Sarah Joseph et al., *The International Covenant on Civil and Political Rights: Cases, Materials, and Commentary* (New York: Oxford University Press, 2000) at 387.

[51] *Ibid.* at 391.

[52] *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, [hereinafter *Universal Declaration*]. Online: http://portal.unesco.org/en/ev/php@URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html Accessed March 24, 2004. The *Universal Declaration* was unanimously endorsed by the United Nations General Assembly on December 9, 1998

> Article 12
>
> a. Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.
>
> b. *Freedom of research, which is necessary for the progress of knowledge, is part of freedom of thought.* The applications of research, including applications in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole. [emphasis added]

The *Préparatoires*[53] to the *Universal Declaration* notes that article 11 specifically cites reproductive cloning "to replicate individuals" as an example of an activity that would be contrary to human dignity, but it makes no reference to therapeutic cloning.[54] With respect to article 12, the *Travaux Préparatoires* notes that paragraph (a) reaffirms an individual's right to enjoy the benefits of scientific progress. This is also included in two of the major human rights texts, i.e., the UDHR and the ICESCR.[55] States are to balance the right to enjoy the benefits of scientific progress with the researcher's intellectual property rights in the research findings. Furthermore, the *Travaux Préparatoires* notes that this principle should be applied and implemented in light of the state's available material and human resources.[56]

The *Travaux Préparatoires* notes that while article 12(b) recognizes that freedom of thought is "indispensable for scientific research and creative activity," it is to be viewed as a corollary to the individual's right to enjoy the benefits of scientific progress. In addition, the *Travaux Préparatoires* refers to UNESCO's *Recommendation on the Status of Scientific Researchers*, which asks states to respect "the autonomy and freedom of research necessary to scientific progress."[57]

The UNESCO *Recommendation on the Status of Scientific Researchers*[58] was adopted by the General Conference on November 20, 1974. Under the heading *The civic and ethical aspect of scientific research*, the document provides that member states should encourage conditions in which researchers have the right to "work in a spirit of intellectual freedom to pursue, expound and defend the scientific truth as they see it."[59]

Principle 37 obliges states to encourage those who employ researchers to allow them freedom to publish the results of their work. The restrictions placed on researchers' rights to publish their findings should be minimized.[60]

The Council of Europe's *Convention on Human Rights and Biomedicine*[61] ("*Convention*") states:

> Article 15 – General rule
>
> *Scientific research* in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being. [emphasis added]
>
> Article 18 – Research on embryos *in vitro*
>
> 1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
>
> 2. The creation of human embryos for research purposes is prohibited.

The *Convention's Explanatory Report*[62] notes that, with respect to article 15, freedom to conduct research is justified by humanity's right to knowledge and by the benefits of such research to patients' health and well-being.[63] Paragraph 96 notes, however, that such freedom is not to be taken as absolute. In the context of medical research, limits provided by other fundamental rights set out in the *Convention*, and other legal concepts such as human dignity, operate as a check on the scientist's conduct and freedom of research.[64]

---

[53] UNESCO Committee of Governmental Experts for the Finalization of a Declaration on the Human Genome, *Final Report Annex I (B)* (Paris, July, 1997) (BIO-97/CONF.201/CLD.6).

[54] *Ibid.* at para. 42.

[55] *Ibid.* at para. 43.

[56] *Ibid.*

[57] *Ibid.* at para 44.

[58] UNESCO, *Recommendation on the Status of Scientific Researchers.* Online: http://www.unesco.org/human_rights/hrcf.htm Accessed March 2004.

[59] *Ibid.* at 6.

[60] *Ibid.* at 9.

[61] *Convention for the Protection of Human Rights and Dignity of The Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, (ETS no. 164) Oviedo, 4.IV.1997.

[62] *Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine. Convention on Human Rights and Biomedicine Explanatory Report* Online: http://conventions.coe.int/Treaty/en/Reports/Html/164.htm.

[63] *Ibid.* at para. 95.

With regard to article 18, the *Explanatory Report* states that paragraph (1) sets out the importance, for those countries that allow research using an *in vitro* embryo, to have legislation in place to adequately protect the embryo.[65] Although the *Convention* does not take a position on embryo research, the second paragraph specifically prohibits the creation of a human *in vitro* embryo for research purposes.[66]

In 1998, the Council of Europe issued an amendment to its *Convention* entitled "*Additional Protocol to the Convention on the Prohibition of Cloning Human Beings*"[67] ("*Protocol*"). Article 1 states that any intervention to create a human being that is genetically identical to another human being is prohibited. The *Explanatory Report to the Protocol* notes that "one has to distinguish between three situations: cloning of cells as a technique, use of embryonic cells in cloning techniques, and cloning of human beings" through embryo splitting or therapeutic cloning.[68]

The Explanatory Report notes that the *Protocol* is not intended to prohibit the cloning of cells and tissue for research purposes to develop medical applications. In fact, the Explanatory Report states that:

> debracloning as a biomedical technique is an important tool for the development of medicine, especially for the development of new therapies. The provisions in this Protocol shall not be understood as prohibiting cloning techniques in cell biology.[69]

The *Protocol* clearly prohibits reproductive cloning to create a human being. Rather than specifically prohibiting therapeutic cloning for research purposes, it notes instead that this process is an important tool for medical research. As noted in Chapter 3, although Canada is not a member of the Council of Europe, it has observer status. In the event of a dispute in Canada, the courts could be referred to the *Convention* and the *Protocol* as examples of how the countries in Europe have dealt with these issues.

In 2000, the European Union proclaimed the *Charter of Fundamental Rights* ("*European Charter*").[70] Article 10 provides the right to freedom of thought. Article 11 provides the right to freedom of expression, including the right to hold opinions and to impart information and ideas without interference by public authority and regardless of frontiers.[71] Article 13 states that "scientific research shall be free of constraint."[72] The Preamble states that the enjoyment of the fundamental freedoms protected by the *European Charter* entails responsibilities and duties to other persons, to the human community and to future generations.[73]

4.5.1.1 Conclusion

Of all the international and regional instruments referred to above, the ICCPR and the ICESCR are the only instruments that are binding on Canada. While the UNESCO instruments and the European Convention are not binding, they can be referred to by the Canadian courts to inform its interpretation of the *Charter* and of domestic law. Often the courts do not make principled distinctions between binding and nonbinding instruments, but seem to selectively refer to instruments for interpretive purposes.

4.5.2 The Law in Other Jurisdictions

The following sets out legislation in the United States ("U.S.") and the U.K. which may impact on researchers' rights.

---

[64] *Ibid.* at para. 96.

[65] *Ibid.* at para. 115.

[66] *Ibid.* at para. 116.

[67] *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings* (CETS no. 168) (Paris, 12.I.1998) (http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm).

[68] *Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings*, "Explanatory Report" (ETS no. 168). Online: http://assembly.coe.int/documents/adoptedtext/ta97/eopi202.htm; http://conventions.coe.int/Treaty/en/Reports/Html/168.htm.

[69] *Ibid.* at para. 4.

[70] European Union, *Charter of Fundamental Rights* . Online: http://europa.eu.int/comm/justice_home/unit/charte/en/charter-preamble.html.

[71] *Ibid.* at Article 11.

[72] *Ibid.* at Article 13.

[73] *Ibid.* at Preamble.

The U.S.

Although federal legislation does not specifically prohibit research on an *in vitro* embryo, there is legislation prohibiting the federal funding of certain research activities. In 1997, President Clinton issued a Presidential Directive prohibiting federal funding by any federal agencies for human cloning.[74] In 1998, the President issued a Statement of Administration Policy supporting an amendment to a Senate bill on cloning that would have prohibited reproductive cloning to produce humans, but permitted therapeutic cloning for the purpose of obtaining embryonic stem cells. The Statement, however, did not have the force or effect of the 1997 Directive.[75]

On August 9, 2001, President Bush announced that federal funding would only be available for research using embryonic stem cell lines that were created prior to that date. This decision meant that federal monies would not be made available to create any new embryonic stem cell lines.[76] This restriction has created problems for American researchers. As of March 14, 2004, there were 78 embryonic stem cell lines approved for federal funding. Concerns have been expressed about the limited value of these stem cell lines since they were grown on and are contaminated with mouse feeder cells, which limit their possible usefulness in therapies to treat humans.[77] If they were intended for transfer into a human, they would have to be treated as a xenotransplant.[78]

Although there are restrictions on federal funding for embryonic stem cell research in the U.S., there is no federal legislation prohibiting therapeutic cloning, embryo splitting or parthenogenesis to derive embryonic stem cells. In February 2003, the U.S. House of Representatives passed the *Human Cloning Prohibition Act*.[79] It would ban all human cloning, both reproductive and therapeutic. At the same time, its companion bill, s. 245, was introduced into the Senate and referred to the Senate Committee on Health, Education, Labour and Pensions.[80] At the time of writing, it is unclear whether there would be enough votes in the Senate to pass s. 245.[81]

Some legislation does exist at the state level. In 1997, California passed a law prohibiting all forms of cloning. Since that time, Rhode Island, Virginia and New Jersey passed similar legislation. Arkansas, Iowa, Michigan, Louisiana and North Dakota have legislation in place prohibiting both reproductive and therapeutic cloning.[82]

In 2002, however, California relaxed its position and passed new legislation promoting stem cell research, including research on stem cells obtained from therapeutically cloned *in vitro* embryos.[83] New Jersey recently followed suit passing legislation that permits therapeutic cloning to obtain embryonic stem cells for research purposes.[84] The New Jersey statute permits research involving the derivation and use of human embryonic stem cells, germ cells and adult stem cells from any source, including therapeutically cloned *in vitro* embryos.[85]

U.S. Constitution

Although there is no specific reference in the *United States Constitution* to a right of scientific inquiry, it is a highly valued principle in the U.S. Scientific theories have been protected because of the American ethos of the "sanctity of knowledge and the value of intellectual freedom."[86]

---

[74] *Supra* note 10 at 37

[75] *Ibid.*

[76] Randall Chase, "Lawmakers want to ease stem cell research restrictions" U.S.A. Today (March 8, 2004). Online: http://www.usatoday.com/tech/news/techpolicy/2004/03/08-stem-cell-petition_x.htm.

[77] *Ibid.*

[78] NIH Human Embryonic Stem Cell Registry. Online: http://stemcells.nih.gov/registry/index.aspOnline. Accessed March, 2004.

[79] *The Human Cloning Prohibition Act* 2003 (HR 534). Online: http://www.humaneventsonline.com/article.php?id=2117.

[80] Office of Legislative Policy and Analysis, "Legislative Updates" (March 9, 2004). This is the same bill only renumbered and introduced into the Senate. Online: http://olpa.od.nih.gov/legislation/108/pendinglegislation/cloning1.asp.

[81] *Ibid.*

[82] National conference of State Legislatures, "State Human Cloning Laws" (Updated: January 6, 2004). Online: http://www.ncls.org/programs/health/Genetics/rt-schl.htm

[83] Suzanne H. Rhodes, "The Difficulty of Regulating Reproductive and Therapeutic Cloning: Can the Unites States Learn Anything from the Laws of Other Countries?" (2003) 21 Penn. St. Int'l L. Rev. 341 at 2 (Lexis Nexis).

[84] Governor James E. McGreevey, News Release, "McGreevey Signs Landmark Stem Cell Research Act" (January 4, 2004); Bionews, "New Jersey 2nd US state to promote stem cell research" (January 12, 2004). Online: http://www.bionews.org.uk/nes.lasso?storyid=1938. Vote on a similar bill is expected in the state of Illinois, and the states of New York and Massachusetts are considering introducing similar legislation.

[85] *Ibid.*

[86] Working Group on Reproductive Technologies, "Symposium on Cloning: Cloning Position Paper of the IIT Institute for Science, Law and Technology" (winter, 1998) 8 s. Cal. Interdis. L.J. 87 at 2 (Lexis Nexis)

Within the American *Bill of Rights*, the First Amendment right to free speech and the Fourteenth Amendment right to personal liberty are considered by some to encompass a constitutionally protected right of scientific inquiry.[87] The U.S. Supreme Court has not had the opportunity to determine whether these rights include a right to research and if so, the scope of that right. The First Amendment provides:

> Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the *freedom of speech*, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.[88] [emphasis added]

The relevant portion of the Fourteenth Amendment provides:

> [n]o state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws."[89]

Case law

In *Branzburg v. Hayes*[90] ("*Branzburg*"), the U.S. Supreme Court extended First Amendment protection to the gathering of the news as a precursor to speech.[91] The Court noted that the informative function of the press is also performed by lecturers, political pollsters, novelists, academic researchers, and dramatists.[92]

In *Buckley v. Valeo*[93] ("*Buckley*"), the U.S. Supreme Court broadly interpreted the First Amendment's freedom of speech to include and protect the *act* of donating money to finance political speech, including the act of donating money to a particular candidate, since it involved the symbolic act of expressing support.[94] In *Meyer v. Nebraska*,[95] the Court held that the right to liberty in the Fourteenth Amendment encompassed the freedom to "acquire useful knowledge... and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."[96]

Summary

Jurisdiction under the American Bill of Rights although not specifically dealing with a right to undertake scientific research, suggests that freedom of speech includes broad rights to inform or communicate (*Branzburg, supra*) and the physical activities association with expression (*Buckley, supra*).

The U.K.

In 2000, the *Donaldson Report*[97] was tabled in Parliament. It contained the findings of an expert group that had been appointed by the government to review and assess the anticipated benefits, risks and alternative of new areas of research using human embryos, and to advise the government as to whether such research should be permitted.[98]

The first recommendation in the *Donaldson Report* was that research using *in vitro* embryos, either supernumerary, created by therapeutic cloning or by fertilization, should be permitted, subject to the controls in the *HFE Act*.[99] The *Donaldson Report* noted that many people in the U.K. have ethical concerns regarding the therapeutic cloning of embryos for research purposes. The expert group stated that the potential benefits of research, using cloned embryos to derive stem cells to treat a number of degenerative disorders, outweighed the ethical concerns. This was especially so because any research would be subject to certain conditions, tight controls, and the oversight of the HFE Authority.

---

[87] *Ibid.* at 2 (Lexis Nexis); Lori B. Andrews, "Is there a Right to Clone? Constitutional Challenges to Bans on Human Cloning" (Summer,1998) 11 Harv. J. Law & Tech. 643 at 9 (Lexis Nexis).

[88] *United States Constitution*, *Bill of Rights*, First Amendment. Online: http://www.law.cornell/edu/constitution/constitution.billofrights.html.

[89] *Ibid.*(Fourteenth Amendment).

[90] *Branzburg v. Hayes et al.*, 408 U.S. 665; 92 s. Ct. 2646; 33 L. Ed. 2d 626 (U.S. Supreme Court).

[91] *Ibid.* at 681-2.

[92] *Ibid.* at 705.

[93] *Buckley v. Valeo*, 424 U.S. 1 (1976) (U.S. Supreme Court).

[94] *Ibid.* at 1218.

[95] *Meyer v. Nebraska*, 262 U.S. 390 (1923) (U.S. Supreme Court).

[96] *Ibid.* at 399.

[97] UK Department of Health, *Stem Cell Research: Medical Progress with Responsibility* (London: Department of Health, 2000). [hereinafter referred to as the *Donaldson Report*].

[98] *Ibid.* at 5.

[99] *Ibid.* at 45.

In 2001, the House of Commons passed regulations to the *HFE Act* permitting the therapeutic cloning of *in vitro* embryos in order to extract stem cells for research purposes. This controversial vote had been delayed pending the outcome of a High Court decision on a ProLife Alliance challenge to the regulations.[100]

The ProLife Alliance sought judicial review of the HFE regulations, specifically that the definition of embryo under the *HFE Act* could not include cloned embryos since they are not created through reproduction. If that were the case, the HFE Authority would not be able to issue licences to allow therapeutic cloning and the retrieval of stem cells for research. The High Court agreed with the ProLife Alliance.[101]

The government appealed, and the Court of Appeal overturned the High Court's decision, by holding a legislative intent to include cloned embryos in the definition. In 2003, the HFE Authority granted its first licence to the Roslin Institute to allow the derivation of stem cells from human *in vitro* embryos.[102]

4.5.3 The Law in Canada

No legislation in Canada provides researchers with a specific right of inquiry or research. Guidance documents set out the ethical principles to be followed by researchers in order to qualify for federal funding, but there are no provisions in the documents that suggest a right to research.

Royal Commission on New Reproductive Technologies

The Royal Commission on New Reproductive Technologies ("Royal Commission") in its 1993 report, entitled *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* ("Final Report"), included a discussion regarding research using human embryos. (The term "zygotes" is used by the Commission.[103]) There is a brief reference to embryonic stem cells under the heading "Future Directions in Embryo Research."[104] The Royal Commission noted that the study of embryonic stem cells could yield important information about cell division which could assist in the understanding of diseases, such as cancer.[105] The scant attention paid to embryonic stem cells is likely due to the fact that they were only successfully derived from *in vitro* embryos and cultured in 1998, well after the completion of the Final Report.[106]

The Final Report did, however, make several general recommendations with respect to research using *in vitro* embryos. For example, the Royal Commission recommended that research on embryos should be restricted to the first 14 days of development, and an *in vitro* embryo should only be used for research when the gamete providers have consented to such a use.[107] With respect to cloning, the Final Report noted in Chapter 22 that during public consultations concerns were raised regarding the possibility that cloning techniques might be used in the future to create human beings.[108]

Tri-Council Policy Statement

In 1998, the three Funding Councils of Canada[109] released their policy statement, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*[110] ("TCPS"). The TCPS sets out the ethical principles to which researchers and research institutions must comply in order to receive government funding.

The TCPS notes that the cardinal principle for research involving humans is respect for human dignity, which forms the basis of the ethical obligations in research.[111] Section 9 sets out the standards or criteria for researchers to apply when researching on human embryos. For example, article 9.4 states that it is unacceptable to create human embryos specifically for research purposes. Article 9.4(a) states that research on *in vitro* embryos that are excess to a person's reproductive needs is ethically acceptable, as long as the persons whose gametes were used to create the embryos have given their free and informed consent and there has been no exchange of money or services for the embryo.[112] Article 9.5 states that it is ethically unacceptable to undertake research that involves the cloning of a human being, including therapeutic cloning.[113]

---

[100] Dr. Kirsty Horsey, "IVF after 25 years: A history of regulation" *Bionews* (11 July 2003). Online: http://www.bionews.org.uk/home.lasso

[101] *Ibid.*

[102] Juliet Tizzard, "Confusion over cloning" *Bionews* (10 June 2003). Online: http://www.bionews.org.uk/home.lasso.

[103] Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Government Services Canada, 1993) at 607. See Chapters 2 and 3 for more detailed discussions of the Royal Commission's Final Report.

[104] *Ibid.* at 618.

[105] *Ibid.*

[106] Thomson JA, J. Itskovitz-Eldor, SS Shapiro, MA Waknitz, JJ Swiergiel, VS Marshall and JM Jones, "Embryonic Stem Cell Lines Derived from Human Blastocysts" Science 1998: 282: 1445-1147.

[107] *Supra* note 103 (Recommendation 183 and 186).

[108] *Ibid.* at 608.

[109] The three Funding Councils are the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada. In 2000, the Canadian Institutes of Health Research replaced the Medical Research Council.

[110] *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 1998) (with 2000, 2002 updates). Online: http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm. Accessed March, 2004.

The Canadian Institutes of Health Research

The Canadian Institutes of Health Research ("CIHR"), a federal funding agency for health research, has published guidelines for research using human stem cells entitled *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research*[114] ("Guidelines"). The Guidelines came into effect on March 4, 2002. They set out the conditions under which the CIHR will fund stem cell research, as well as the types of research that will not be eligible for funding.[115]

Article 1 of the Guidelines states that the TCPS applies to all research and institutions that receive funding from the CIHR.[116] Article 4 states that a Stem Cell Oversight Committee will be established to conduct an ethical review of all stem cell research proposals. In order to receive funding, stem cell research proposals must be approved by this committee.[117] Article 5 states that the CIHR will establish a stem cell registry consisting of all human embryonic stem cell lines generated using research funds from the CIHR.[118]

Article 7.1 provides a list of research activities that are eligible for CIHR funding. Research to derive and study embryonic stem cells will be eligible for funding, provided that the embryos were originally created for reproductive purposes, became supernumerary and were donated to research.[119]

Article 7.4 contains a list of research that will not be funded. Research involving the creation of an *in vitro* embryo solely to derive stem cells, as well as research involving therapeutic cloning, will not be eligible for funding.[120]

It is important to note that neither the TCPS nor the Guidelines apply to privately funded research in Canada. Only research funded by the government is required to comply with these principles.

The Assisted Human Reproduction Act

Certain parts of the *Assisted Human Reproduction Act*[121] ("*AHR Act*") were proclaimed in force on April 22, 2004. This included a majority of the prohibitions, including prohibitions against the creation of a cloned *in vitro* embryo and against the creation of an *in vitro* embryo for research purposes (sections 5(1)(a) and (b) of the Act). A contravention of the prohibitions could result in significant penal sanctions based on the federal criminal law head of power in section 91(27) of the *Constitution Act, 1867*.

Sections 5(1)(a) and (b) of the Act states:

> 5. (1) No person shall knowingly
>
> a. create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;
>
> b. create an in vitro embryo for any purpose other than creating a human being or improving or providing instruction in assisted human reproduction;

---

[111] *Ibid.* at i.5.

[112] *Ibid.* at 9.2.

[113] *Ibid.* at 9.3.

[114] Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (Effective March 4, 2002). Online: http://www.cihr-irsc.gc.ca/e/1487.html Accessed March 2004. These Guidelines do not have the force of law and are not the product of "rule-making" in the technical sense, but they apply to all human pluripotent stem cell research funded by the CIHR, thereby affecting much of advanced research in Canada.

[115] *Ibid.* at 2.

[116] *Ibid.*

[117] *Ibid.* at 3.

[118] *Ibid.*

[119] *Ibid.* at 4.

[120] *Ibid.* at 8.

[121] *An Act Respecting Assisted Human Reproduction and Related Research*. Third Session, Thirty-Seventh Parliament, 52-53 Elizabeth II, 2004 (passed 12 March 2004 and certain sections proclaimed in force 22 April 2004). Online: http://www.parl.gc.ca.

Section 60 of the Act provides:

> 60. A person who contravenes any of sections 5 to 9 is guilty of an offence and
>
> a. is liable, on conviction on indictment, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding ten years or to both; or
>
> b. is liable, on summary conviction, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding four years, or to both.

Section 5(1)(b) provides a very narrow exemption to the prohibition on creating an *in vitro* embryo for research purposes. It allows the creation of an *in vitro* embryo for research if the purpose is to improve the health and safety of assisted human reproduction ("AHR") procedures for women or embryos.

The *AHR Act* allows research on supernumerary *in vitro* embryos, including research to derive embryonic stem cells. The researcher will require a licence from the future Assisted Human Reproduction Agency ("Agency") and the Agency will have to be satisfied that the use of a human *in vitro* embryo is necessary for the proposed research project (s. 40(2) of the Act).

Although the *AHR Act* prohibits therapeutic cloning and embryo splitting, it is silent with respect to research using embryonic stem cells obtained from such embryos. That is because such research is beyond the scope of the *AHR Act* which is primarily about assisted reproduction.

As noted earlier, the CIHR Guidelines provide that only research using stem cells obtained from supernumerary *in vitro* embryos will be eligible for federal funding. It should be noted, however, that the CIHR Guidelines do not have the force of law but rather provide criteria necessary for researchers to meet if they wish to receive government funding. Research that is privately funded is not required to comply with the Guidelines.

The *Canadian Charter of Rights and Freedoms*

The *Canadian Charter of Rights and Freedoms* ("*Charter*") protects freedom of expression. Section 2(b) of the *Charter* provides:

> 2. Everyone has the following fundamental freedoms:
>
> b. freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication;

The rights and freedoms set out in the *Charter* are not absolute. The state can limit *Charter* rights and freedoms, as long as it can justify the limitation as reasonable in a free and democratic society. Section 1 of the *Charter* states:

> 1. The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Case law

The following discussion provides some of the leading jurisprudence regarding freedom of expression in section 2(b) of the *Charter*. This jurisprudence would be relevant to the courts consideration of a claim regarding a possible *Charter*-protected right to research.

In *Irwin Toy v. Québec (Attorney General)* ("*Irwin Toy*"),[122] the Supreme Court of Canada was asked, among other things, whether Quebec's legislation prohibiting advertising directed at persons under the age of 13 years, violated section 2(b) of the *Charter*. A majority of the Court held that the legislation constituted limitations on freedom of expression, but that such limitations were justified by the government under section 1 of the *Charter*.[123]

In reaching its decision, a majority of the Court made the following comments about freedom of expression:

> "Expression has both a content and a form, and the two can be inextricably connected. *Activity is expressive if it attempts to convey meaning*. That meaning is

---

[122] *Irwin Toy v. Québec (Attorney General)*, [1989] 1 S.C.R. 927.

[123] *Ibid.* at 979 and 1000.

> its content. Freedom of expression was entrenched in our Constitutiondebrato ensure that everyone can manifest their thoughts, opinions, beliefs, indeed all expressions of the heart and mind, however unpopular, distasteful or contrary to the mainstream. Such protection is... "fundamental" because in a free, pluralistic and democratic society we prize a diversity of ideas and opinions for their inherent value both to the community and to the individualdebraFor Rand J. of the Supreme Court of Canada, it was "little less vital to man's mind and spirit than breathing is to his physical existence"... And as the European Court stated... freedom of expression... is applicable not only to "information" or "ideas" that are favourably received or regarded as inoffensive or as a matter of indifference, but also to those that offend, shock or disturb the State or any sector of the population. Such are the demands of [sic] that pluralism, tolerance and broadmindedness without which there is no "democratic society."[124] [emphasis added]

The majority noted that the approach to freedom of expression should be broad and inclusive.[125] Activity that conveys or attempts to convey a meaning in a non-violent form of expression would fall within the *Charter*-protected sphere of conduct.[126]

In *R. v. Butler* ("*Butler*"), [127] the respondent had been charged under the *Criminal Code* with various counts of selling and possessing obscene material for the purposes of sale or distribution. The Supreme Court of Canada was asked whether certain published and video materials that depicted sexual activity for sale and rent in Mr. Butler's store met the *Criminal Code* definition of obscene. Mr. Butler alleged that the *Criminal Code* provision violated his *Charter* guarantee of freedom of expression.[128]

The trial judge held that the obscene material was protected by the guarantee of freedom of expression in section 2(b) of the *Charter*. The judge convicted Butler on some charges and acquitted him on others. The Crown appealed. A majority of the Court of Appeal allowed the appeal and convicted Butler on all counts. The Court held that the materials in question fell outside the protection of the *Charter* since they constituted purely physical activity and involved undue exploitation and degradation of human sexuality.[129]

Butler appealed. The Supreme Court held that the Court of Appeal erred in concluding that because the materials in question depicted purely physical activity, they fell outside of *Charter* protection under section 2(b). The Supreme Court stated that just because the subject matter of the materials is physical activity, "debrathis does not mean that the materials do not convey or attempt to convey meaning such that they are without expressive content."[130] The Court referred to the example, provided in *Irwin Toy, supra,* of parking a car, which although a physical activity, could be regarded as conveying a message. In that case, the Court concluded that purely physical activity, such as parking a car, could be undertaken to protest an unfair method of assigning parking spaces and thus convey a message.[131] In allowing Butler's appeal, the Supreme Court noted that activities cannot be excluded from the scope of the guaranteed freedom on the basis of the content or meaning being conveyed.[132] In addition, the Court stated that "the content of a statement cannot deprive it of the protection accorded by section 2(b), no matter how offensive."[133]

In *R. v. Keegstra* ("*Keegstra*"),[134] the Supreme Court of Canada was asked whether the *Criminal Code* provision, making the wilful promotion of hatred against identifiable groups a criminal offence, infringed the right to freedom of expression in section 2(b) of the *Charter*. The defendant, a high school teacher, had taught his students that Jews had "created the Holocaust to gain sympathy," and that they were "deceptive, secretive and inherently evil." His students were expected to reflect these views in their papers and exams if they wished to get good grades.[135]

A majority of the Supreme Court held that the *Criminal Code* provision infringed freedom of expression. In so finding, the majority stated that "the term 'expression' as used in section 2(b) of the *Charter* embraces all content of expression irrespective of the particular meaning or message sought to be conveyed."[136] The majority held that the legislative provision prohibited communications which convey meaning, in this case communications intended to promote hatred against the Jews, and thus infringed Keegstra's right to freedom of expression guaranteed by the *Charter*.[137] However, because the government justified the infringement, under section 1 of the *Charter*, the *Criminal Code* provision was held to be constitutionally valid.[138]

---

[124] *Ibid.* at 968-969.
[125] *Ibid.* at 970.
[126] *Ibid.* at 931.
[127] *R. v. Butler*, [1992] 1 S.C.R. 452.
[128] *Ibid.* at 453.
[129] *Ibid.* at 486-7.
[130] *Ibid.* at 487.
[131] *Ibid.*
[132] *Ibid.* at 488.
[133] *Ibid.*
[134] *R. v. Keegstra*, [1990] 3 S.C.R. 697.
[135] *Ibid.* at 714.

Justice McLachlin, as she was then, wrote the dissent in *Keegstra*. She noted that freedom of expression is the pivotal freedom on which all other rights and freedoms depend. "Without the freedom to comment and criticize, other fundamental rights and freedoms may be subverted by the state."[139] McLachlin J. affirmed the importance of freedom of expression to the marketplace of ideas where although truth may not always emerge, that "does not negate the essential validity of the… value of the marketplace of ideas."[140]

On reviewing the jurisprudence, she noted that to determine the scope of freedom of expression, it is necessary to consider the benefits to be gained from the pursuit of truth and creativity in *science*, art, industry and other endeavours. Justice McLachlin noted that the guarantees to freedom of expression found in international instruments, such as the ICESCR and the European *Convention for the Protection of Human Rights and Fundamental Freedoms*, explicitly permit a wide variety of limitations on the freedom, unlike the *Charter*, which provides a more comprehensive guarantee.[141]

Advocating a broad interpretation of section 2(b), McLachlin J. noted that if freedom of expression is curtailed by the state:

> debra[s]cientists may well think twice before researching and publishing results of research suggesting difference between ethnic or racial groups… even political debate on crucial issues such as immigration, educational language rights, foreign ownership and trade may be tempered. These matters go to the heart of the traditional justifications for protecting freedom of expression.[142]

In *Little Sisters Book and Art Emporium v. Canada (Minister of Justice)* ("*Little Sisters*"),[143] a gay and lesbian bookstore, charged with importing erotica from the U.S. contrary to the *Customs Act*, alleged that the Act infringed its freedom of expression under section 2(b) and its equality rights under section 15 of the *Charter*. In concluding that the legislative provisions infringed section 2(b), a majority of the Supreme Court noted that:

> debrafreedom of expression is central to our identity as individuals and to our collective well-being as a society. Doubt about justification should be resolved in its [freedom of expression] favour.[144]

Finally, in *R. v. Sharpe* ("*Sharpe*"),[145] the Supreme Court was asked whether possession of expressive material contrary to the *Criminal Code*, in the form of child pornography, is protected by the right to freedom of expression in section 2(b) of the *Charter*. A majority of the Court held that the mere possession of child pornography was protected by the right to freedom of expression and, in this case, the Court held that the government failed to justify the *Criminal Code* offence, under section 1 of the *Charter*.

McLachlin C.J., writing for the majority, noted that some of the values protected by a guarantee to freedom of expression include artistic creativity, education, *medical research* or other public purposes.[146] In reaching a decision, Chief Justice McLachlin noted:

> Among the most fundamental rights possessed by Canadians is freedom of expression. It makes possible our liberty, our creativity and our democracy. It does this by protecting not only "good" and

---

[136] *Ibid.* at 729.
[137] *Ibid.* at 730.
[138] *Ibid.* at 786.
[139] *Ibid.* at 802-3.
[140] *Ibid.* at 803.
[141] *Ibid.* at 807.
[142] *Ibid.* at 860.
[143] *Little Sisters Book Emporium v. Canada (Minister of Justice)*, [2000] 2 S.C.R. 1120.
[144] *Ibid.* at para. 144.
[145] *R. v. Sharpe*, [2001] 1 S.C.R. 45. Chief Justice McLachlin wrote the majority opinion in *Sharpe*. Her broad interpretation of freedom of expression is evident in her dissent in *Keegstra*, *supra*, and her reasoning for the majority in *Sharpe*.
[146] *Ibid.* at para. 60.

> popular expression, but also unpopular or even offensive expression. *The right to freedom of expression rests on the conviction that the best route to truth, individual flourishing and peaceful coexistence in a heterogeneous society in which people hold divergent and conflicting beliefs lies in the free flow of ideas and images.* If we do not like an idea or an image, we are free to argue against it or simply turn away. But, absent some constitutionally adequate justification, we cannot forbid a person from expressing it.
>
> [...]
>
> Nevertheless, freedom of expression is not absolute. Our Constitution recognizes that Parliament... can sometimes limit some forms of expression. Overarching considerations, like the prevention of hate that divides society... or prevention of harm that threatens vulnerable members of our society... may justify prohibitions on some kinds of expression in some circumstances... however, any attempt to restrict the right must be subjected to the most careful scrutiny.[147] [emphasis added]

The Chief Justice described section 2(b) as providing a continuum of intellectual and expressive freedom, consisting of "freedom of thought, belief, opinion and expression."[148] She noted that the right to possess expressive material is:

> debraintegrally related to the development of thought, belief, opinion and expressiondebra[W]ithout the right to possess expressive material, freedom of thought, belief, opinion and expression would be compromised.[149]

4.5.4 Academic Literature and Other Commentary

The issue of cloning and embryonic stem cell research has generated a substantial amount of academic writing and commentary at both the national and international levels. In 2001, the International Bioethics Committee ("IBC") of UNESCO issued its final report entitled *The Use of Embryonic Stem Cells in Therapeutic Research* ("UNESCO Report").[150] The UNESCO Report provides a description of the science and potential therapeutic applications of embryonic stem cells, and the various religious, ethical and philosophical positions regarding stem cell research.[151]

It notes that any debate on these issues will evoke strong positions and convictions making it very difficult for a State to reach a consensus.[152] The IBC concludes that individual States must initiate dialogue on these issues amongst its citizens to identify which positions to adopt. If a State permits these research activities, it should ensure that they can only be conducted within a state-sponsored regulatory framework which provides appropriate guidelines and ensures the assessment of ethical considerations. States should facilitate research into alternative sources for stem cell lines, such as adult stem cells and therapeutic cloning.[153] Finally, the UNESCO Report concludes that research involving the embryo should be carried out in accordance with the principles set out in the UDHR and the *Universal Declaration on the Human Genome and Human Rights*.[154]

At least one Canadian academic, Barbara Billingsley, has examined a possible ban on therapeutic cloning as a source of embryonic stem cells in the context of freedom of expression. Billingsley queries whether a federal prohibition on therapeutic cloning would constitute an unjustifiable violation of a person's *Charter*-protected right to freedom of expression.[155] Billingsley notes that the Supreme Court of Canada has not had the opportunity to determine whether scientific or medical research constitutes "expression" under section 2(b) of the *Charter*.[156] However, she observes that the Court has generally defined "expression" to "include any activity which conveys or attempts to convey meaning and which is non-violent."[157]

---

[147] *Ibid.* at para. 21-22.

[148] *Ibid.* at para. 25.

[149] *Ibid.*

[150] International Bioethics Committee, UNESCO, "The Use of Embryonic Stem Cells in Therapeutic Research" (BIO-7/00/GT-1/2 (Rev. 3) Paris (April 6, 2001).

[151] *Ibid.* at 1-8.

[152] *Ibid.* at 9.

[153] *Ibid.* at 12-13.

[154] *Ibid.* at 14.

[155] Barbara Billingsley, "A Constitutional Analysis of the Proposed Ban on Non-Reproductive Human Cloning: An Unjustified Violation of Freedom of Expression?" (2002) 11 Health L. Rev. No. 1 at 32-39 (QL).

[156] *Ibid.* at 3 (QL).

[157] *Ibid.* (QL).

Billingsley notes that to date the Court has taken a broad "content neutral" approach to the right in section 2(b). The Supreme Court considers this right important enough for constitutional protection since it allows people to seek and attain truth, to participate in social and political decision-making and to pursue individual self-fulfilment and flourishing. As long as an activity related to one of these purposes is communicative, it will be protected under section 2(b), even if the expression has little moral value, such as hate propaganda and child pornography.[158]

Billingsley ponders whether the courts would consider therapeutic cloning to constitute expression, i.e., does it attempt to communicate a meaning. Neither the Supreme Court of Canada nor the U.S. Supreme Court has considered whether medical research constitutes expression.

One could argue that the physical process of creating a cloned embryo is non-communicative. Billingsley argues, however, that the process could be viewed as communicative since it is essentially a response to an inquiry or a hypothesis. The physical experiment is undertaken in an attempt to respond to the inquiry or to test the hypothesis, "for the purpose of communicating a meaning or a message to the researcher."[159] These purposes are in accordance with the underlying purposes of section 2(b), i.e., the pursuit of truth, self-fulfilment and societal advancement.[160]

Billingsley suggests that the experiment or process itself may be viewed as communicating a message. The researcher, by undertaking the research, communicates to others the message that he or she believes that therapeutic cloning and stem cell research have the potential to offer a cure for certain diseases.[161] In the alternative, she argues that the physical activity necessary for therapeutic cloning could be considered to be inseparable from the expressive activity of recording or disseminating the results of such research. It is clear that one can't have research results without first having conducted the research.

Billingsley notes that the Supreme Court has specifically held that violent activity will not be protected by section 2(b). She ponders whether the courts might consider the derivation of stem cells from a cloned human embryo as a violent activity since it requires the intentional destruction of the *in vitro* embryo.[162] In *Keegstra, supra,* the SCC stated that for the purposes of section 2(b), violence is "expression communicated directly through physical harm."[163] This may depend on whether the courts would consider the destruction of an *in vitro* embryo to be either violence or even murder.[164]

There is much American commentary on the possibility that a legislated ban on human cloning would infringe researchers' First Amendment right to free speech and/or their Fourteenth Amendment right to personal liberty. While some academic commentators argue that there is no constitutional right to engage in scientific research, such as the derivation of embryonic stem cells, others argue that the courts would find that scientific inquiry is protected speech under the First Amendment.

Before examining American academic commentary on the U.S. freedom of speech, it is important to highlight a significant distinction between the *Charter* and the *United States Constitution*. Section 1 of the *Charter* provides the state with an opportunity to justify an infringement as a reasonable limitation in a free and democratic society. For example, section 1 of the *Charter* made it possible in *Keegstra, supra,* for the state to justify the *Criminal Code* restriction on hate speech. The *United States Constitution* does not contain a similar "balancing" provision, making it often more difficult for the state to justify a limitation on freedom of speech.

John Robertson, a law professor and prolific academic writer, has authored what some may consider the seminal paper on this topic.[165] He undertakes a very thorough and detailed discussion as to whether the First and/or Fourteenth Amendments to the *United States Constitution* include a right of scientists to undertake research.

Professor Robertson begins by noting that scientific research has two dimensions that must be distinguished.

---

[158] *Ibid.* (QL).
[159] *Ibid.* at 5 (QL).
[160] *Ibid.*(QL).
[161] *Ibid.* (QL).
[162] *Ibid.* at 5-6 (QL).
[163] *Ibid.* at 6 (QL).
[164] *Ibid.* at 7 (QL).
[165] John A. Robertson, "The Scientist's Right to Research: A Constitutional Analysis" (1978) 51 s. Cal. L. Rev. 1203.

One dimension is related to the choice of research *topic* – the particular knowledge that the researcher wishes to develop, while the other dimension concerns the *means* to pursue the research – the means or techniques for generating the data or conclusions that will verify or disprove a hypothesis and thus generate knowledge.[166]

Freedom of research would engage a number of rights or freedoms, such as freedom of thought, freedom to communicate one's thoughts, ideas, explanations and conclusions, freedom to gather or generate data in ways that conform to scientific inquiry, including the freedom to experiment, i.e., to manipulate or arrange human and non-human agents and substances to generate data essential to the development of new knowledge.[167] He notes that the researchers' right to research is a negative right to be free from government intervention in the choosing of research topics and the choosing of the means to carry out the research. The freedom to choose the method of research would include the freedom to experiment. The corresponding duty on the government is a negative duty not to interfere, rather than a positive duty to fund or facilitate research.[168]

The researchers' right to experiment would not be absolute. Professor Robertson suggests that although the researcher would be free to choose any means of conducting the research that is scientifically sound, they may not cause direct, substantial harm to the cognizable interests of others. In his view, most scientists would agree that the right to undertake scientific inquiry includes the right to choose the means of research, as long as external harm is slight and the property or personal interests of the manipulated material are not violated.[169]

Professor Robertson posits that restrictions that limit the researchers' freedom to select the topic of research generally result from a judgement that certain categories of scientific knowledge will reveal truths that it would be preferable not to know, or that may lead to techniques or applications that may have harmful consequences. These restrictions may be found in legislation and licensing systems. In his view, they clearly limit the right of scientific inquiry and research, and thus bear a heavy burden of state justification to be found valid.

The second type of restriction limits the manner by which research ends may be pursued. In this case, scientists can pursue any topic they choose, but are restricted in the methods they may select. Generally speaking, these restrictions are intended to protect interests threatened by the scientific process used to generate the essential data. This type of restriction may pose a less serious threat to the right to scientific inquiry, especially if there is an alternate method for conducting the research that is not restricted by the state.[170]

Robertson examines whether there is a constitutional right to undertake research. He notes that even if the courts held that there was such a constitutionally protected right, it would have to yield to overriding public interests, as is the case with the rights of journalists, speakers, parents, or pregnant women, when the exercise of their rights imposes sufficiently heavy costs on others.[171] He suggests and discusses in detail a number of constitutional sources for the right to research, including the right to personal liberty and privacy in the Fourteenth Amendment, the right of free association, and the right to free speech in the First Amendment. The right to free speech was recently found by the U.S. courts to contain a right to receive or acquire information and ideas from a willing source, and the right to gather news. He notes that the courts have recognized in these two emerging doctrines, protection for the prior stages essential to speech, i.e., receiving information and newsgathering, which in his view could logically be extended to provide constitutional protection to the conduct of research with materials or willing sources.[172]

Of particular interest is his discussion under the right to free speech. The commentary and jurisprudence regarding the U.S. constitutional right to free speech might be referred to Canadian courts to inform their interpretation of the *Charter* right to freedom of expression. Professor Robertson notes that the U.S. Supreme Court considers the First Amendment's primary concern to be with ensuring that citizens have a full opportunity for expression in all its varied forms to convey a desired message. "Full opportunity for expression serves both individual and societal ends – the individual's interest in the information necessary for social and political decision making."[173]

---

[166] *Ibid.* at 1204.
[167] *Ibid.* at 1205.
[168] *Ibid.* at 1206.
[169] *Ibid.* at 1207.
[170] *Ibid.* at 1207-8.
[171] *Ibid.* at 1209.
[172] *Ibid.* at 1212, 1214, 1215, and 1219.

In Robertson's view, scientific knowledge and information are clearly within the protection of the First Amendment. He bases this view, in part, on the fact that science provides information relevant to a wide range of decisions – from individual to state decisions. For example, scientific information may inform individual choices regarding the purchase of certain products and it doubtlessly informs government policy making.[174]

Professor Robertson sets out two main arguments for including a right to research within the right to free speech. First, he argues that most of the activities associated with scientific research have been traditionally protected by the First Amendment, such as speaking, talking, writing, and publishing.[175]

Second, he argues that those aspects of research involving non-traditional forms of expression, such as experimentation, would also be protected. This is because the activity of research involves the production of information or knowledge to communicate to others and is an essential step in the process of dissemination of information and ideas, and thus would also qualify for constitutional protection. Without research there would be no dissemination of scientific information or knowledge. If research was not protected, government could easily restrict the dissemination of information and ideas by restricting the research itself. He notes:

> debrait must follow that even earlier stages in the publication process are protected. Otherwise, government could control access to ideas by placing restraints at the point where the information is initially developed or obtained.[176]

Professor Robertson concludes that research activities intended to produce knowledge for dissemination must therefore be protected as free speech.[177] He does not explore in depth the type of state restrictions on a right to research that might withstand a constitutional challenge. Rather, he suggests that under the First Amendment, state restrictions could be justified on the basis that the research posed a threat to health or safety, or interfered with the rights of non-consenting persons.[178]

American Roger Taylor also suggests that protection for research could flow from the First Amendment's safeguarding of the "marketplace of ideas."[179] In his view, based on First Amendment jurisprudence, the courts would probably treat experimentation on embryos as conduct containing both "speech" and "non-speech" aspects. Experimentation involves the recording and disseminating of results, both of which are elements of speech.[180]

Taylor speculates that it would be difficult for the state to define a ban on therapeutic cloning narrowly enough to survive a constitutional challenge. In his view, this is because the state's interest in protecting the *in vitro* embryo is likely less important when the embryo has no real potential for human life. In his view, *in vitro* embryos that have been cloned for therapeutic research purposes represent potential life only in a symbolic sense.[181] Dolly, the reproductively cloned ewe, was the result of many failed attempts at reproductive cloning. He concludes that it is likely that cloning a human *in vitro* embryo for reproductive purposes would meet with similar difficulties when attempting to create a viable embryo with potential for human life.

Taylor concludes that because *in vitro* embryos created by means of therapeutic cloning "have so miniscule, perhaps only theoretical or symbolic, potential for life, the importance of the state interest in them may be insufficient for a ban on therapeutic cloning."[182] In his view, however, reasonable state regulation that does not amount to a ban would likely survive constitutional scrutiny since it would promote the government's interest in medical standards and ethics.[183]

---

[173] *Ibid.* at 1215; *Saxbe v. Washington Post Co.*, 417 U.S. 50, 76 (1976).
[174] *Ibid.* at 1216.
[175] *Ibid.* at 1217.
[176] *Ibid.*
[177] *Ibid.* at 1218.
[178] *Ibid.* at 1279.
[179] Roger H. Taylor, "The Fear of Drawing the Line at Cloning" (2003) 9 B.U. J. SCI. & TECH. L. 379 (Lexis Nexis).
[180] *Ibid.* at 4 (Lexis Nexis).
[181] *Ibid.* at 5 (Lexis Nexis).
[182] *Ibid.* (Lexis Nexis).

Another American commentator, Cass Sunstein, examines the issue from the perspective of a patient and argues that because there is no constitutional right to select a medical treatment, there is no fundamental right to engage in therapeutic cloning.[184] He limits his examination of such a possible right to the constitutional guarantee of privacy and liberty rather than to the constitutional right to free speech.

Sunstein suggests that the argument for a presumptive constitutional right to clone for therapeutic purposes would be extremely weak. At the same time, he suggests that the government's justification for intruding on a person's freedom of choice would also be quite weak.[185] The central argument is whether there is a constitutional presumptive right to select medical treatments. Doctors, scientists and patients might argue that there is such a right protected by the constitutional right to privacy. The state cannot interfere with a personal choice to select a particular medical treatment that is crucial to one's well-being. The difficulty with these arguments is that no Supreme Court decision has suggested the existence of such a right.

He cites the U.S. Supreme Court's recent decision supporting a ban on physician-assisted suicide and suggests that since individuals do not have the right to choose death, they must surely not have a right to access a particular set of medical experiments that might ultimately assist them to live.[186] The best state justification for a ban on therapeutic cloning is that it assists in making the ban on reproductive cloning effective.[187] Sunstein did not, however, undertake an analysis of therapeutic cloning from the perspective of the research scientist and the First Amendment's guarantee of free speech.

Law Professor Lori Andrews examines the issue from the perspective of a scientific researcher.[188] She notes that if such a ban were implemented, one possible constitutional challenge would be that it unduly interferes with the right of scientific inquiry. Scientific inquiry is considered to be somewhat sacred in the U.S. Andrews points out that the framers of the *United States Constitution*, concerned in the late 18th century with ensuring the promotion of scientific inquiry, provided authority for a system of patents. In her view, if the First Amendment protects the "marketplace of ideas," it would likely equally protect the generation of information found in the marketplace.[189]

Professor Andrews notes, however, that even if therapeutic cloning were protected by the *United States Constitution*, the state would likely be permitted to impose certain limitations. She speculates that there might be a distinction to be made between the right to pursue knowledge and the right to choose the method of scientific inquiry, which could be legitimately regulated to a certain extent. This would be the case if the method chosen by the researcher threatened an interest in which the state had a legitimate concern, such as health and safety.[190]

In an article written for the *Southern Methodist University Law Review*, Kimberly Jackson examines the constitutional implications of federal cloning legislation.[191] In her view, a complete ban on human cloning raises constitutional issues regarding free speech and free thought. Does the U.S. have constitutional authority to ban a whole area of scientific inquiry? She argues that the freedom to undertake scientific research could be viewed as falling within the First Amendment's guarantee of free speech.[192] The U.S. Supreme Court's decision in *Griswold v. Connecticut*[193] ("*Griswold*") held that the First Amendment's protection of free speech includes "debrathe right to read and freedom of inquiry, freedom of thought, and freedom to teach."[194]

Jackson argues that scientific research and experimentation are part of the communication process itself and thus could be viewed as activities protected by the guarantee of free speech. She suggests that "scientific speech" would be strongly protected under the traditional constitutional analysis for free speech and this protection would also extend to the publication of research results and the exchange of ideas. The difficulty arises with respect to the actual physical research. If one views research as only an action and not a communication, then traditional analysis would likely hold that it is not protected by the First Amendment. Jackson notes, however, that an argument could be made that the physical activity of research is a "building block of communication" and thus should be afforded constitutional protection under free speech.[195]

---

[183] *Ibid.* (Lexis Nexis).

[184] Cass R. Sunstein, "Conceiving a Code for Creation: The Legal Debate Surrounding Human Cloning: Is There a Constitutional Right to Clone?" (2002) 53 Hastings L.J. 987 at 10 (Lexis Nexis).

[185] *Ibid.* at 2 (Lexis Nexis).

[186] *Ibid.* at 10 (Lexis Nexis).

[187] *Ibid.* at 12 (Lexis Nexis).

[188] Lori B. Andrews, "Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning" (1998) 11 Harv. J. Law & Tec. 643 (Lexis Nexis).

[189] *Ibid.* at 9 (Lexis Nexis).

[190] *Ibid.* at 10 (Lexis Nexis).

[191] Kimberly M. Jackson, "Well Hello Dolly! The Advent of Cloning Legislation and Its Constitutional Implications" (1999) 52 SMU L. Rev. 283 (Lexis Nexis).

[192] *Ibid.* at 5 (Lexis Nexis).

[193] *Griswold v. Connecticut*, 381 U.S. 479 (1965) (U.S. Supreme Court).

[194] *Supra* note 191 at 6 (Lexis Nexis).

Matthew Hsu examines this view of research activity in "Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or an Unconstitutional Restriction of Symbolic Speech?"[196] He notes that a literal reading of the First Amendment suggests that it would only protect speech and not conduct. However, the U.S. Supreme Court has "long recognized" that these protections extend beyond verbal or written communication.[197]

He notes that in *Spence v. Washington*,[198] the Supreme Court concluded that "when conduct is sufficiently imbued with elements of communication," it will receive the same protection as speech under the First Amendment.[199] In fact, this protected conduct is referred to as "expressive conduct" or "symbolic speech."[200] Hsu notes that the courts will not protect all conduct, but rather only conduct that is intended to convey a "particularized message" that would most likely be understood by those in receipt of the message.[201]

Hsu suggests that for human cloning to receive First Amendment protection, the activities related to cloning must contain sufficient elements of speech to raise it to the level of symbolic speech. The conduct must express an idea, and because the First Amendment protects scientific ideas, the scientist's ability to conduct scientific research must also be protected. One could argue that the intent of the scientific research is to test a scientific theory. This conduct is necessary to prove or disprove an assertion made as a written theory. In the area of scientific research, experimentation is the conduct necessary to express ideas. Scientists engage in experimentation to express ideas, i.e., to prove or disprove a particular scientific theory. He concludes that because a cloning experiment would also test a hypothesis, it should be considered symbolic speech and thus protected by the First Amendment.[202]

Roy Spence and Jennifer Weizierl propose a different approach to scientific research and free speech.[203] They discuss critiques of the assertion that scientific research is protected speech. They refer, for example, to Professor G. Francione who rejects the notion that scientific research is expression or expressive conduct under the "marketplace of ideas" model.[204]

Francione argues that scientific experimentation does not become expressive conduct just because it facilitates the scientific process. He finds nothing inherent in the physical activity of experimentation that could be characterized as expression or expressive conduct. He notes that the U.S. Supreme Court in *Clark v. Community for Creative Non-Violence*[205] implied that "purely facilitative conduct would not be covered by the First Amendment."[206] If an experiment lacks any communicative aspects, then the mere fact that it is facilitative to scientific speech does not make it expressive conduct and thus worthy of First Amendment protection.[207]

Spece and Weizierl posit that scientific experimentation or inquiry is protected since it is a central and unique part of a highly favoured process. This process is imbued with direct communicative processes, as well as conduct that can properly be considered expressive because of its essential part in the truth-searching enterprise.[208] The authors point out that harmful scientific conduct would not be protected by the First Amendment. In their view, any medical or scientific experiment that would violate a person's rights should not receive *prima facie* constitutional protection.[209]

---

[195] *Ibid.* (Lexis Nexis).

[196] Matthew B. Hsu, "Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or an Unconstitutional Restriction of Symbolic Speech?" (1999) 87 Geo. L.J. 2399 (Lexis Nexis).

[197] *Ibid.* at 4 (Lexis Nexis).

[198] *Spence v. Washington*, 418 U.S. 405 (1974) (U.S. Supreme Court).

[199] *Ibid.* at 409; *supra* note 193 at 4.

[200] *Barnes v. Glen Theatre*, 501 U.S. 560, 567 (1991) (U.S. Supreme Court); *supra* note 196 at 4 (Lexis Nexis).

[201] *United States v. O'Brien*, 391 U.S. 367 at 376 (1968) (U.S. Supreme Court); *supra* note 196 at 5 (Lexis Nexis).

[202] *Supra* note 196 at 6 (Lexis Nexis).

[203] Roy G. Spece and Jennifer Weinzierl, "First Amendment Protection of Experimentation: A Critical Review and Tentative Synthesis/Reconstruction of the Literature" (1998) 8 s. Cal. Interdis. L.J. 185 (Lexis Nexis).

[204] Gary L. Francione, "Experimentation and the Marketplace Theory of the First Amendment" (1987) 136 U. Pa. L. Rev. 417.

[205] *Clark v. Community for Creative Non-Violence*, 468 U.S. 288 (1984) (U.S. Supreme Court).

[206] *Supra* note 203 at 206.

[207] *Ibid.* at 207.

The authors concede that certain distinct aspects of scientific inquiry might not on their own be considered expression. However, when those distinct aspects are considered along with those parts of the scientific process that are clearly communicative, then logically both should be entitled to constitutional protection. As an example, they note that mixing cells in a Petrie dish might not be considered to constitute expression when viewed in isolation, but would nonetheless be protected as expressive conduct since the conduct is necessary to the scientist's pursuit of knowledge, which is part of the scientific method.[210]

A further example cited by the authors is the facilitative relationship between "association" and "political speech." Political speech is highly valued in the U.S., but would be meaningless without an ability to reach a large audience. The courts have generally protected conduct that facilitates political speech, such as association and political funding of a candidate (*Buckley, supra*).[211]

Scientific speech is also highly valued and deeply imbedded in American tradition. Thought and experimentation have been recognized as nurturing aspects of scientific speech.[212] The authors point out that the courts have held that First Amendment protection covers both thought and mentation generally.[213] They argue that mentation and experimentation are synergistic since each activity gives rise to and is complementary of the other. In their view, the courts should protect experimentation that is uniquely related to and bound up with the important process of mentation and scientific discovery.[214]

4.5.5 Discussion

The pursuit of scientific inquiry has not always been considered a highly valued activity in society. Galileo (b. 1564) greatly improved on the first telescope and undertook experiments to prove his various scientific theories. In fact, circa 1590, he published *De Motu*, a series of essays on the theory of motion, advocating a revolutionary new idea: one can test theories by conducting experiments.

Galileo's publications were not appreciated by all of society. In 1633, the Church was so threatened by some of his theories that it condemned him for heresy for publishing and defending his belief that the Earth orbited around the Sun. Over time, many of Galileo's theories have been proven by others to be correct and today his scientific writings are highly valued.[215]

The framers of the Canadian *Constitution* and the framers of the *United States Constitution* included provisions either in the written constitution or the accompanying documents relating to the issuing of patents, an act illustrating the importance society was beginning to recognize and place on scientific inquiry and experimentation. One important purpose served by the patent regime is to encourage scientific inquiry and invention by granting the inventor a monopoly to capitalize on his or her invention.

Scientific inquiry and research are credited today with finding cures and treatments for countless life-threatening diseases and disorders, such as diabetes, polio, and smallpox. Without the ability for scientists and doctors to freely investigate and experiment, many cures and treatments would not have been discovered. However, rights to medical and scientific research should not be viewed as absolute rights.

The rights and freedoms provided in the *Charter* are not absolute, but rather must be balanced against other interests in society. The state can and does impose limitations on certain rights and freedoms in order to protect society-at-large. In the case of research on human participants, for example, the state would be justified in limiting a researcher's right to conduct such research if it was likely to result in harm or a threat to public health and safety.

---

[208] *Ibid.* at 214.

[209] *Ibid.*

[210] *Ibid.* at 215.

[211] *Ibid.* at 216.

[212] *Ibid.* at 217.

[213] *Ibid.* at 219. The authors cite in their analysis: *Stanley v. Georgia*, 394 U.S. 557 (1969), *United States v. Reidel*, 402 U.S. 351 (1971), and *Bowers v. Hardwick*, 478 U.S. 186 (1986).

[214] *Ibid.* at 218-9.

[215] J.J. O'Connor and E.F. Robertson, "Galileo Galilei". Online: http://www-gap.dcs.st-and.ac.uk/~history/Mathematicians/Galileo.html.

Could the state prohibit research?

As noted earlier, several international and regional instruments reflect the importance of freedom of expression. Article 19(2) of the ICCPR suggests that the right to expression is broad; it includes oral, written and published communication. In addition, the article suggests that freedom of expression includes the right to actively seek information and ideas. One could argue this international human right suggests protecting the discovery of new knowledge, information, and ideas to disseminate to others, activities characteristic of scientific research. Article 19(3) notes, however, that freedom of expression is not limitless. The state would arguably be justified in limiting activities related to freedom of expression, if they posed a threat to public health or morals.

Article 15 of the ICESCR appears to be more explicit, obliging States Parties to provide scientists with the freedom to conduct research and recognizing the link between scientific freedom and research. The *Universal Declaration* also emphasizes the importance of freedom of research, while at the same time providing limits on research.

All of the international and regional instruments, cited above, note that the right to engage in scientific and medical research is not absolute.[216] Research must be undertaken in a manner that respects the human rights of research participants, such as requiring their free and informed consent prior to participation. Furthermore, research should conform to established ethical principles, such as respect for human dignity.

It is possible to conclude that the state can prohibit scientific research. If the state prohibited scientific research, researchers might look to the *Charter* for relief and might refer the courts to certain provisions in international human rights instruments and regional instruments to advocate an interpretation of freedom of expression that includes scientific inquiry.

Could a researcher claim that a state prohibition on scientific inquiry infringes his or her Charter-protected right to freedom of expression?

The Supreme Court of Canada has given freedom of expression an expansive and generous interpretation under section 2(b) of the *Charter*. In *Irwin Toy, supra*, the Court noted that its broad approach to freedom of expression would include activity that conveys or attempts to convey a message, as long as it does so in a non-violent manner.

In *Sharpe, supra*, Chief Justice McLachlin described the rights in section 2(b) as existing on a continuum, ranging from thought, at one end of the continuum, to expression, at the other end. Possession of expressive material was found to be a protected physical activity since it was integrally related to the development of the rights in the continuum. Finally, in the words of the Chief Justice, any government attempt to restrict the right to freedom of expression will be subjected by the Court "to the most careful scrutiny."[217] The case law serves to illustrate the generally expansive interpretation the Court has given to this freedom and provides an indication of the importance the judiciary ascribes to freedom of expression.

Freedom of the press and other media of communication are explicitly protected by section 2(b). It is most likely that scientific research in the form of publications, videos, lectures, dialogue, and other forms of communication would similarly be protected by Canadian courts under section 2(b). A strong argument could be made that the published results of scientific research would be protected expression, under the phrase "other media of communication." Any state restriction on a scientist's attempts to publish his or her research results would undoubtedly engage his or her *Charter* right to freedom of expression. Although unlikely, the state might be able to successfully justify a prohibition on the publication of research results in exceptional circumstances, the state's legislative objective would have to be pressing and substantial.

On occasion, the courts have cited scientific research as an example of values protected by the guarantee to freedom of expression.

---

[216] For an example, see article 15 of the Council of Europe *Convention on Human Rights and Biomedicine*.

[217] *Supra* note 145 at para. 21-22.

Would section 2(b) protect that part of the research that is mainly physical, i.e., the experiment itself?

In the U.S., the courts have found that the First Amendment's freedom of the press also protects the journalist's, and perhaps even the public's, right to gather news and information from willing sources.[218] This appears to be a logical interpretation of the scope of the freedom because if the physical act of gathering the news was not protected and could be restricted by the state, it would undoubtedly limit the journalist's freedom of the press. Applying the same logic to scientific research, if the right to experiment was not protected by freedom of expression, the right to publish or disseminate research results and scientific knowledge could be similarly limited by the state.

Relevant provisions in international and regional instruments suggest that the physical component of scientific inquiry, i.e., experiment or research, should also be protected under freedom of expression. For example, the *Travaux Préparatoires* to the *Universal Declaration* notes that there is an essential physical component to scientific research.[219]

The Supreme Court has held that "conduct" is also protected by section 2(b) of the *Charter* as long as it conveys, or attempts to convey, a message in a non-violent way. In the words of Peter W. Hogg:

> Is there any activity that is not expression under the Court's definition? The answer is not much, because "most human activity combines expressive and physical elements"; what is excluded is that which is "purely physical and does not convey or attempt to convey meaning."[220]

Even if the courts found the message conveyed by certain research activities to be offensive, it would still be protected. The protection offered by section 2(b) is content-neutral: the conduct will be protected as long as it is expressive and non-violent.

The carrying out of an experiment could be seen as conduct that expresses or attempts to express an opinion or belief that a particular experiment will yield a certain result. Furthermore, the experiment itself might be viewed as an expressive activity since it communicates a response to the researcher's question or hypothesis.

It has been suggested that the physical aspect of scientific research, i.e., the physical experiment, could also be viewed as an essential building block of communication. Without the physical activity necessary to conduct the experiment, there could be no research results or reliable answers to scientific questions. If the physical aspect of scientific research was prohibited by the state, arguably the state would also be prohibiting scientific thought, inquiry and expression.

Justice McLachlin, as she was then, advocated a broad interpretation of section 2(b) noting that if freedom of expression is curtailed by the state "debra[s]cientists may well think twice before *researching and publishing* results of research... "[221] [emphasis added] This statement suggests that the courts might find that both activities would be protected under section 2(b), i.e., the physical aspect of research and the publishing of research results.

Chief Justice McLachlin, in *Sharpe, supra,* noted that the right to physically possess expressive material was essential and integrally related to the development of thought, belief, opinion and expression. A strong argument could be made that the right to conduct an experiment is integrally related to the development of scientific thought, belief, opinion and expression.

The courts might consider some types of research using human embryos, such as the derivation of embryonic stem cells, as violent activity since it causes the destruction of the embryo. However, this is unlikely given the fact that *in vitro* embryos used in research are required by the AHR Act to be destroyed prior to the fourteenth day. Furthermore, individuals or couples who have excess *in vitro* embryos in storage may legally choose, as one means of disposition, to allow them to perish rather than donate them to others for reproductive or research purposes. In addition, under the common law, the *in vitro* embryo is not considered a person and as such, has no legal rights, such as the right to life.

---

[218] *Branzburg v. Hayes*, 408 U.S. 655 (1972); *Pell v. Procunier*, 417 U.S. 817, 834 (1974); *Saxbe v. Washington Post Co.*, 417 U.S. 843, 862-64 (1974).

[219] *Supra* note 53.

[220] Peter W. Hogg, *Constitutional Law of Canada* (Loose-leaf Ed.) (Scarborough: Carswell Thomson Publishing, 1997) at 40.5(a).

[221] *Supra* note 134 at 860.

On the other hand, an argument could be made that the experiment portion of scientific research is purely physical activity, with no elements of expressive conduct whatsoever. A researcher's freedom to express scientific theories and hypothesis could be protected by section 2(b) of the *Charter*, but the physical experiment portion of research would not be protected and thus would be subject to unlimited state restriction. This argument is not too convincing given the comments made by the Supreme Court regarding research, albeit in *obiter dicta*,[222] and the Court's broad approach to the rights protected by section 2(b) of the *Charter*. Such a distinction, if permitted, would allow the state to indirectly restrict the researcher's right to publish findings and scientific knowledge by directly restricting his or her ability to conduct the necessary physical component of scientific inquiry, i.e., the experiment.

If the courts found experimentation to be a communicative activity or expressive conduct, protected by the *Charter*, it could then be argued that such research relates to two of the three purposes of expression described by the Court. Research arguably serves the purpose of personal self-fulfillment for the researcher, and assists researchers to seek and attain the truth regarding a hypothesis or scientific query.

Unlike the American jurisprudence under freedom of speech, the *Charter* provides the state with an explicit opportunity under section 1 to justify any limitation on freedom of expression. If the state's justification passes the judicial test under section 1, then the restriction would be found to be constitutionally valid.

A state prohibition on research using embryonic stem cells

As noted earlier, the U.S. prohibits federal funding for research on stem cells derived from *in vitro* embryos created through any method of embryo *cloning*. However, federal funds may be used for research using stem cells derived from supernumerary *in vitro* embryos. For researchers seeking federal funding in Canada, the CIHR imposes similar restrictions on the use of embryonic stem cells. The restriction in Canada, unlike the U.S., does not have the force of law. Privately funded research in both the U.S. and Canada may be undertaken using stem cells derived from therapeutically cloned *in vitro* embryos.

For the purposes of the following discussion, an assumption is made that Canada has passed a law prohibiting research on embryonic stem cells. Such a prohibition would restrict Canadian researchers from an area of research expected to result in medical therapies and cures for debilitating and life-threatening human diseases in the not too distant future.

The prohibition could be challenged by researchers on the basis that it constitutes an unjustified limitation on their freedom of expression in section 2(b) of the *Charter* and is thus unconstitutional. An argument would be made that freedom of expression is broad and encompasses the researcher's choice of research topic, as well as the physical conduct of the research.

The Supreme Court has stated that conduct will only be protected under section 2(b) if it conveys or attempts to convey a message. What message would a researcher be conveying or attempting to convey by experimenting on embryonic stem cells?

The researchers would have to identify a specific message that the physical experiment was intended to convey to the scientist. If they succeed in articulating a message, the physical conduct of the research, i.e., the experiment, may be considered "expression" worthy of *Charter* protection. The courts might consider that the state prohibition on the activity of embryonic stem cell research is in effect preventing the researcher from expressing certain scientific information to others. The research is prevented by the state from contributing certain scientific knowledge and ideas to the marketplace of ideas. In addition, the physical research might be viewed as a right integrally related to the development of thought, belief, opinion and expression and thus worthy of *Charter* protection.

---

[222] "*Obiter dicta*" is a Latin term meaning a judge's expression of opinion uttered in court or giving judgement, but not essential to the decision and therefore without binding authority (Concise Oxford Dictionary, 10th Ed.)

It may be possible for the state to justify its restriction on embryonic stem cell research on the basis of protecting public morals. The derivation of embryonic stem cells results in the destruction of the *in vitro* embryo. The state's objective is to protect the *in vitro* embryo since it represents potential human life. Allowing such research would result in the destruction of *in vitro* embryos and would arguably diminish society's respect for the sanctity of human life. Researchers would be creating potential human life, represented by the therapeutically cloned *in vitro* embryo, to serve solely as a source of research materials.

4.5.6 Conclusion

The Supreme Court has taken a very broad interpretive approach to freedom of expression in section 2(b) of the *Charter*. In addition, freedom of expression is viewed by the Supreme Court as *the* pivotal freedom underlying democracy. State limitations on this freedom will receive the most careful scrutiny by the courts when they are challenged.

However, the Supreme Court does not consider this fundamental freedom to be absolute. As the case law illustrates, the state can successfully justify limitations on freedom of expression in order to balance competing societal interests.

If scientific research using embryonic stem cells was found to be expression and protected by section 2(b) of the *Charter*, it would then fall to the state to successfully argue, under section 1 of the *Charter*, that the prohibition is a reasonable limit, prescribed by law, and demonstrably justified in a free and democratic society.

4.6 Issue 2: The Right to Benefit from Scientific Progress

Assuming that a prohibition on embryonic stem cell research would engage a researcher's section 2(b) *Charter* right to freedom of expression, would such a prohibition also implicate other rights? If such research was prohibited by the state, would those persons expecting to benefit from medical therapies and cures resulting from the research argue that their human rights are also engaged? Is there a human right to benefit from scientific progress?

4.6.1 International and Regional Instruments

With respect to international human rights instruments, article 15(1)(b) of the ICESCR provides:

> 1. The States Parties to the present covenant recognize the right of everyone:
>
>   a. to take part in cultural life;
>
>   b. to enjoy the benefits of scientific progress and its applications;
>
>   c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

There is very little academic literature or commentary regarding the scope of the rights or the State obligations that flow from article 15(1)(b). In addition, there is no reference to this right in Canadian jurisprudence.[223]

Some commentators suggest that the rights in (b) and (c) must be balanced against each other. The right in (b) is not unlimited: it must be balanced against the rights of the inventor or author as set out in (c). Canadian courts could be faced with an argument that individuals have a right to access the benefit of technology, without state interference and the article above could be relied on to inform the courts interpretation of the *Charter* and of the legislative prohibition. Given the lack of commentary and jurisprudence at the international level, it is unclear as to how the courts in Canada would interpret these provisions.

4.6.2 The Law in Other Jurisdictions

No legislation in the U.S., Germany or the U.K. gives effect to the rights set out in article 15 of the ICESCR.

4.6.3 Academic Literature and Commentary

There is a dearth of commentary on what meaning should be assigned to the international right to enjoy the benefits of scientific progress in the ICESCR.

---

[223] See Chapter 2 at 19.

Cook, et al. suggest that this right serves the goal of other human rights, such as the right to found a family, and the right of persons to enjoy the highest attainable standard of health. [224] The authors argue that this right would include physical and mental health, as well as social well-being.[225]

The authors note that the right to health is currently regarded as more of a negative right than a positive right, meaning that although an individual may have a right to freely access medical therapies, the state is not under a positive obligation to publicly fund such services.[226]

4.6.4 The Law in Canada

No Canadian legislation gives effect to this international right and principle. Neither is there a *Charter* right to enjoy the benefits of scientific progress.

Section 7 of The *Charter* provides the right to life, liberty and security of the person. It states:

> 7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the fundamental principles of justice.

With respect to the "liberty" interest in section 7 of the *Charter*, the courts have determined that it has two aspects. The first aspect protects a person's interest in his or her physical liberty. This interest would be engaged if a person was physically restrained by the state, for example through imprisonment or even the threat of imprisonment, or where the state affects a person's ability to move freely, such as compelling a person to give oral testimony.

The second aspect of section 7 protects a sphere of autonomy within which a person may make decisions of a fundamentally personal nature that go to the core of what it means to enjoy individual liberty and independence. Decisions by persons as to the location of their residence or by parents respecting a child's education or health care are examples of fundamental choices protected by the courts under this aspect of section 7.

Section 7 also protects a person's security of the person interest. Security of the person also contains two aspects. The first aspect concerns the person's interest in physical integrity. Physical integrity protects a person's right to be free from punishment or the threat of punishment by the state. The second aspect concerns psychological integrity. To constitute a breach of this right, the state action must result in a serious and profound effect on the person's psychological integrity. It must be more than ordinary stress or anxiety and must be assessed objectively from the viewpoint of a person of reasonable sensibility. It does not, however, have to be so severe that it causes nervous shock or psychiatric illness.

It is important to note that the courts' analysis under section 7 is in two parts. First the courts determine whether there is a real or imminent deprivation of life, liberty or security of the person. This inquiry may require the courts to consider whether the interest identified and claimed by the plaintiff falls within of the rights. Second, the courts determine whether the state deprivation is in accordance with the principles of fundamental justice. If it is, then there has been no violation or infringement. If the deprivation is not in accordance with the principles of fundamental justice, then a violation has occurred. The courts may or may not require the state to justify a violation under section 1 of the *Charter*.

Case law

In *Godbout v. Longueuil (City)*[227] ("*Godbout*"), the municipality had in place a resolution that required employees to sign a declaration that they would live within the city boundaries during the course of their employment. If the employee moved our of the city during that time, they could be fired without notice.[228] The resolution was challenged on the basis that it violated either the Charter of Quebec or the Canadian *Charter*.[229] Justice LaForest, writing for L'Heureux-Dube and McLachlin J.J., held that the right to liberty in section 7 includes "debrawithin it a right to make fundamentally personal choices free from state interference and that choosing where to establish one's home falls within the scope of that right."[230] He concluded that the residence requirement violated section 7 and was not in accordance with the principles of fundamental justice.[231]

---

[224] Rebecca Cook, Bernard Dickens and Mahmoud F Fathalla, *Reproductive Health and Human Rights: Integrating Medicine, Ethics and Law* (Oxford: Oxford University Press, 2003) at 359.

[225] *Ibid.*

[226] *Ibid.* at 360.

[227] *Godbout v. Longueuil (City)*, [1997] 3 S.C.R. 844.

[228] *Ibid.* at para.16.

[229] *Ibid.* at para.19.

Subsequent jurisprudence has confirmed that the liberty interest protects both aspects, i.e., physical and a protected sphere of decision-making autonomy. In the recent case of *Siemens v. Montreal (Attorney General)*[232] ("*Siemens*"), a majority of the Supreme Court held that while section 7 encompasses fundamental life choices, it does not include pure economic interests.[233]

In *Singh v. Minister of Employment and Immigration*[234] ("*Singh*"), the Supreme Court of Canada held that the phrase "security of the person" in section 7 includes the right to be from the threat of physical punishment or suffering, as well as the right to be free from the punishment itself.[235]

In *New Brunswick (Minister of Health and Community Services) v. G.(J.)*[236] ("*G(J)*"), the Supreme Court was asked whether section 7 applies outside the penal context to ensure that a parent has a right to state-funded legal counsel in a child custody/protection hearing. With respect to the parent's security of the person interest, the Court noted that a restriction will be made out where the impugned state action has a profound and serious effect on a person's psychological integrity.[237] The effect of the state action must be assessed objectively from the perspective of a person of reasonable sensibility. The stress does not have to constitute nervous shock or psychiatric illness, but it must be more than ordinary stress or anxiety.[238] Justice Lamer, writing for the majority, held that state removal of a child constituted a serious interference with the psychological integrity of the parent.[239]

R. v. Monney[240] was concerned with whether a customs search for narcotics constituted an unconstitutional interference with the right to bodily integrity under section 7. the Court noted that in *Singh, supra*, it was held that state action which has the likely effect of impairing a person's health engages the fundamental right under section 7 to security of the person.[241] The Court concluded, however, that in this case the right to security of the person did not include a state obligation to provide medical supervision in response to the respondent's self-induced health risk, notwithstanding the fact that the respondent had refused medical attention.[242]

In *R. v. Parker*,[243] the Ontario Court of Appeal held that the prohibition on the cultivation and possession of marijuana, in the *Narcotic Control Act* and the *Controlled Drugs and Substances Act*, was unconstitutional. The appellant produced evidence in the lower court of the medicinal value of marijuana for a number of serious conditions, including epilepsy. The government argued that the appellant did not need marijuana to control his seizures since he had legal access to alternative therapies. The lower court held that the appellant required marijuana to control his epileptic seizures and that the prohibition against marijuana violated his rights under section 7 of the *Charter*.[244]

The Ontario court of Appeal held that preventing Parker from using marijuana to treat his physical condition by threat of criminal prosecution constitutes interference with his physical and psychological integrity. It prevents him from making choices concerning his own body and control over his physical and psychological integrity free from interference by criminal prohibition.[245]

4.6.5 Discussion

The absence of commentary and jurisprudence regarding the right to enjoy the benefits and applications of scientific progress in the ICESCR makes it difficult to speculate as to how the courts in Canada would be informed, if at all, by this international principle. The commentary above suggests that the right to enjoy the benefits of scientific progress must be balanced with the intellectual property rights of inventors.[246]

---

[230] *Ibid.* at para. 58.

[231] *Ibid.* at para. 91.

[232] *Siemens v. Manitoba (Attorney General)*, [2003] 1 S.C.R. 6.

[233] *Ibid.* at para. 45.

[234] *Singh v. Minister of Employment and Immigration*, [1985] 1 S.C.R. 177.

[235] *Ibid.* at para. 207.

[236] *New Brunswick (Minister of Health and Community Services) v. G.(J.)*, [1999] 3 S.C.R. 46.

[237] *Ibid.* at para. 60.

[238] *Ibid.*

[239] *Ibid.* at para. 61.

[240] *R. v. Monney*, [1999] 1 S.C.R. 652.

[241] *Ibid.* at para. 55.

[242] *Ibid.*

[243] *R. v. Parker*, 2000 CanLII 5762 (ON C.A.)

[244] *Ibid.* at paras. 5 and 6.

[245] *Ibid.* at paras. 109 and 110.

However, a state prohibition on research would not require balancing since there is no concern with infringing an inventor's intellectual property rights. Rather, the question is whether the right to enjoy the benefit of scientific progress and advancement could be used by the Canadian courts to inform their interpretation of Charter rights or of domestic legislation.

As noted in Chapter 2, an examination of the text of the ICESCR provision and the *Travaux Préparatoires* to the ICESCR has led one academic to suggest that article 15(1)(b) contains four core elements.[247] Two of the four core elements are applicable to this discussion. One of these elements would restrict the right to only socially beneficial science, as opposed to harmful science. The other applicable element would ensure that the benefits of scientific progress and its applications are enjoyed equally by everyone.[248]

States are encouraged to promote the provisions of the ICESCR through legislation and regulations. The principle in article 15(1)(b) encourages State Parties to ensure that the benefits of scientific progress and advancement are made available to everyone. State action restricting access to such benefits might be viewed as state action contrary to the principles set out in a binding international human rights instrument.

The underlying premise of the ICESCR could be characterized as promoting scientific research and advancement to relieve human suffering, but only where human dignity and human rights are protected. Those parts of article 15 which espouse the benefits of scientific research should be balanced against articles 10 and 11 which clearly establish, as paramount, the principle of respect for human dignity.

An important aspect of human dignity is autonomy, especially with respect to decision-making that affects the integrity of one's own body. A decision to access new technologies and therapies, resulting from scientific and medical research, for a life threatening disease or condition could be viewed as a fundamentally personal choice going to the core of individual independence and dignity.

Would a state prohibition on certain scientific research or experimental therapy engage any human rights issues?

A state prohibition on scientific research using embryonic stem cells in medical therapies could engage the interests of seriously ill persons whose access to such therapies might be beneficial.

If the state prohibition was backed by penal sanctions, it could be challenged on the basis that it engages the liberty and security of the person interests of such persons under section 7 of the *Charter*. Reference could be made to article 15(1)(b) of the ICESCR which provides the right to enjoy the benefits of scientific progress and its applications. This international provision could be used by the courts to inform its interpretation of the rights under section 7, specifically the right to liberty and to security of the person. An argument could be made the right "to enjoy the benefits of scientific progress" includes the right to choose to undergo an experimental medical therapy when one's life is threatened. A prohibition on this right would engage a person's liberty interest in section 7 of the *Charter*.

If the state deprived seriously ill persons of access to an experimental therapy, it would have to do so in accordance with the principles of fundamental justice. The complainant might identify arbitrariness and overbreadth as the relevant principles of fundamental justice, and allege that the prohibition is not in accordance with these principles. The complainant might also argue that the state's prohibition is not related to a reasonable apprehension of harm. The state may be required to justify the deprivation as reasonable under section 1 of the *Charter*.

4.6.6 Conclusion

Although the *Charter* does not contain a specific right to benefit from scientific progress, it does guarantee to individuals the right to life, liberty and security of the person in section 7. If a person were denied access to a promising but experimental medical therapy by a state-imposed restriction backed by penal sanctions, it would engage that person's section 7 *Charter* rights.

---

[246] See the discussion in Chapter 2 of the Project paper with respect to the balancing between access to scientific advancement and the rights related to intellectual property.

[247] *Ibid.* at 19.

[248] *Ibid.*

The international right to enjoy the benefits and application of scientific progress could be referred to the courts to inform its interpretation of section 7 *Charter* rights and of the domestic legislation. The lack of commentary as to the interpretation of this international provision arguably minimizes its usefulness and makes it difficult to predict how the court would interpret and use the provision. The state would have an explicit opportunity to justify any infringement of a section 7 right under section 1 of the *Charter*.

4.7 Issue 3: The *In Vitro* Embryo

Many activities in the area of AHR are related to the creation, use, manipulation, testing and destruction of human *in vitro* embryos. The legal status of the *in vitro* embryo is discussed in chapters 2 and 3. Both chapters noted that the courts have not yet determined the status of the *in vitro* embryo, or whether the *in vitro* embryo, existing as it does outside the body of a woman, possesses any legal or human rights.

As noted earlier, there are a number of different methods of obtaining or creating *in vitro* embryos for research purposes, including creation, donation of supernumerary embryos, therapeutic cloning, embryo splitting, and parthenogenesis. The following discussion examines whether the method used to create an *in vitro* embryo is a relevant factor or consideration in determining the embryo's moral status.

4.7.1 The Law in Other Jurisdictions

The U.S.

In 1999, the U.S. National Bioethics Advisory Counsel ("NBAC") recommended federal funding for research on spare *in vitro* embryos, but not for research using *in vitro* embryos created solely for research purposes.[249] Since 2001 there has been federal legislation prohibiting the funding of research to create or use an *in vitro* embryo as a source of embryonic stem cells. Federal funding can only be used for research on existing stem cells that were isolated from an *in vitro* embryo prior to August 9, 2001. There are additional conditions on a researcher's use of existing stem cell lines. For example, the embryo from which the stem cell line was derived must have already been destroyed and thus would have no potential for further development.[250] There is no federal legislation or regulations applicable to the use of embryos in privately funded research.

At the state level, there is legislation in several states that prohibits both reproductive and therapeutic cloning. However, California and New Jersey have legislation that specifically permits the creation of *in vitro* embryos for research purposes.

Germany

In Germany, *in vitro* embryos cannot be created or used for research purposes. However, embryonic stem cells can be imported for research. Under the German *Law for the protection of embryos*,[251] the *in vitro* embryo is protected and has legal rights from the moment of creation.

The U.K.

The U.K. allows the creation of *in vitro* embryos, by *in vitro* fertilization and therapeutic cloning, for research purposes with the explicit consent of the gamete donors. The U.K.'s Donaldson Report examined research on embryos, including on embryonic and adult stem cells, and recommended that research using such embryonic stem cells be allowed, along with therapeutic cloning of *in vitro* embryos as one source of such stem cells.

The Donaldson Report acknowledged that there are differing opinions as to the morality of research on a human *in vitro* embryo. It noted:

> Research involving embryos created by cell nuclear replacement [therapeutic cloning] raises new concerns for many people, including those opposed to all embryos research and possibly some of those in the middle ground. Even those who accept the current research uses of embryos might express

---

[249] Cloning Human Beings Report and Recommendations of the National Bioethics Advisory Committee (1997) at 5. Online: http://www.georgetown.edu/research/nrcb/nbac/pubs/cloning1/cloning.pdf; *supra* note 179 at 3.

[250] *Supra* note 23 at 132.

[251] *Law for the protection of embryos*, Bundesgesetzblatt, Part 1, 19 December 1990, pp. 2736-2748.

> concern about the research use of embryos created in this way. Such embryos can be seen as being created as a means to an end and for use as a product source.

An alternative view is that the benefits of being able to develop an individual's own cells to create a new source of cells for their own future treatment make this action ethically justifiable. While research on embryos created by cell nuclear replacement does indeed involve using them as a means to an end, this can be said to apply to some degree to all research using embryos. The potential benefits of the research need to be weighted against these concerns… these benefits would be substantial and may represent the best prospect of developing treatments for a number of degenerative disorders.[252]

Canada

The AHR Act prohibits the creation of an *in vitro* embryo for research purposes, as well as the cloning of an *in vitro* embryo for reproductive or research purposes. The Royal Commission on New Reproductive Technologies noted in its 1993 Final Report to Parliament that *in vitro* embryos are deserving of respect, not solely because of their potential for human life, but based mainly on their connections to the human community.[253]

4.7.1.1 Summary

There is wide disparity between jurisdictions as to the moral and legal status of the *in vitro* embryo. It could be said that the U.K., by allowing the creation of *in vitro* embryos solely for research purposes, is at one end of the moral status continuum, while Germany, which assigns legal rights to the *in vitro* embryo from the moment of conception, is at the opposite end.

The U.S. federal government's view of the moral status of an *in vitro* embryo is similar to that of Germany. However, there are U.S. states that explicitly permit the creation of *in vitro* embryos solely for research purposes. Canada, with the adoption of the AHR Act, has assumed a mid position on the continuum by permitting research on supernumerary *in vitro* embryos, but prohibiting the creation of embryos solely for research purposes.

4.7.2 Academic Commentary

Professor John Robertson discusses both the moral and legal status of the *in vitro* embryo.[254] He notes that early embryos, while less developed than fœtuses, are genetically unique, living human entities that have the potential to develop into full persons.[255]

With advances in technology and the possibility of fertilization of a human egg with sperm in a dish in a laboratory, issues have arisen as to whether limits should be placed on external creation, storage, discard and manipulation of *in vitro* embryos. Robertson notes that only a small portion of fertilized eggs develop to the blastocyst stage – only one embryo in ten actually implants in the mother's womb and of those, thirty to forty percent are spontaneously aborted.[256]

He sets out a number of differing viewpoints as to the moral status of *in vitro* embryos, which range from a belief that the embryo is a human life possessing legal rights at the moment of fertilization to a view that, even at the latter stages of development, a prenatal human entity does not have any rights. Robertson notes that, despite these different views, most people believe that the embryo should be treated with special respect because it is genetically unique, living human tissue that has the potential to develop into a fœtus and a newborn. He argues that it is precisely because the embryo is genetically unique and has the potential to develop, that it operates as a "powerful symbol" of the unique gift of human existence.[257]

Even though the embryo is not itself a rights-holder or a moral subject, it stimulates consciousness of the human community more than any other human tissue. However, Robertson argues that, unlike other symbols such as a national flag, whether the *in vitro* embryo is considered as a symbol of membership in the human community is a matter of choice, not moral duty.[258]

---

[252] *Supra* note 97 at 8.

[253] *Supra* note 103 at 633.

[254] John A. Robertson, "Reproductive Technology and Reproductive Rights: In The Beginning: The Legal Status of Early Embryos" (1990) 76 Va. L. Rev. 437. (Lexis Nexis).

[255] *Ibid.* at 1 (Lexis Nexis).

[256] *Ibid.* at 3 (Lexis Nexis).

[257] *Ibid.* at 4 (Lexis Nexis).

In his view, because of the rudimentary development of the early embryo and its slim chances of implanting and coming to term, it is a less powerful symbol of human community than would be the more developed fœtus. Other symbols in society require individuals to subscribe to a unified view of the symbol as a criterion for membership, such as the American flag or membership in the national community. Divergent views of the embryo are more likely and more acceptable precisely because of its low potential for developing into a human being. Robertson argues that the question of whether the special respect assigned to early embryos must always be maintained is a factor of the competing interests that must be considered when questions of embryo disposition arise. He notes that views about research using *in vitro* embryos would, more than any other dispositional decision, most likely depend on one's views about the moral status of the embryo. "The issue of greatest controversy is whether embryos could be created solely for research purposes and then discarded with no intention or possibility of placement in the uterus."[259]

In Robertson's view, given that the research and discard of therapeutically cloned embryos would occur at the same stage of development as supernumerary *in vitro* embryos, donated for research, the origin of the embryo should be irrelevant. He suggests that strong policy arguments exist for permitting and supporting many types of embryo research under the system of Institutional Review Board approval and supervision. "There are compelling reasons for allowing embryos to be created for research purposes and then discarded, as this may be the only way to conduct many important kinds of research."[260]

Kimberly Jackson considers whether a cloned embryo can be considered unique human life.[261] She suggests that while both *in vitro* fertilization and therapeutic cloning can be considered "unnatural reproductive technologies," only *in vitro* fertilization results in the creation of a new and unique individual. Cloning merely creates a copy of an already existing individual.[262]

Roger Taylor suggests that unlike the deoxyribonucleic acid ("DNA") of an embryo created through *in vitro* fertilization, by the fusion of a sperm and an egg, the DNA of a therapeutically cloned embryo is not in any way unique. It is a copy of the DNA of an already existing person (the nucleus donor). He ponders why it is that research on supernumerary *in vitro* embryos receives less protection than research on cloned embryos.[263] In his view, one would think logically that it should be the reverse.

The embryo created through *in vitro* fertilization has the potential to develop into a unique human person with an open future. On the other hand, the cloned human embryo may not possess the potential to develop into a human being and even if it did, it would not be unique and would not have an open future.[264]

David Smolin argues that the significance differences between therapeutically cloned embryos and embryos created by the fusion of sperm and egg result in an ambiguous moral status for the cloned embryo. He begins by discussing the ambiguities that science and medicine have recently created around the status of the early reproductive embryo.[265]

First, he notes that most embryos are lost in the natural reproductive process through a failure to implant in the uterus. Second, medicine has shifted the definition of pregnancy from fertilization to implantation. Third, modern birth control drugs prevent implantation, thus causing the destruction of any embryos. Fourth, society has accepted *in vitro* fertilization, which results in the discarding of many embryos per successful birth.[266]

With respect to the cloned embryo, he notes that cloning is an artificial form of asexual reproduction. Cloning does not involve conception. In addition, the constituent parts of the cloned embryo are a human egg (devoid of a nucleus) and the nucleus of a somatic cell, neither of which have ever been considered to constitute an individual human life.[267] In Smolin's opinion, if the cloned embryo cannot literally be considered an individual human life, then the symbolic value of protecting it may be outweighed by the ethical obligation to use it in research to find cures to heal and save lives.[268]

---

[258] *Ibid.* (Lexis Nexis).

[259] *Ibid.* at 21-2 (Lexis Nexis).

[260] *Ibid.* at 22 (Lexis Nexis).

[261] *Supra* note 191.

[262] *Ibid.* at 6.

[263] *Supra* note 179 at 9.

[264] *Ibid.*

[265] David M. Smolin, "Should a Ban on Reproductive Cloning Include a Ban on Cloning for Purposes of Research or Therapy?" (2001/2002) 32 Cumb. L. Rev. 487 at 5.

[266] *Ibid.* at 6.

Not everyone shares this viewpoint. James McCartney[269] argues that creating embryos as sources of stem cells, either by *in vitro* fertilization, cloning or parthenogenesis, is ethically problematic.[270] He believes that ethicists would argue that creating human life for research is tantamount to using human life as a means only. However, in McCartney's view, the developing embryo is not an individual of the human species until approximately the fourteenth day post-fertilization when the primitive streak appears.[271]

McCartney posits, however, that since these embryos are on their way toward becoming human individuals, they should be treated with reverence and accorded respect. They should not be created solely for the purposes of scientific research that would result in their destruction. He acknowledges that this view is not as strong as the view that embryos possess inalienable rights, such as the right to life. However, he believes it is sufficient to support ethical opposition to the creation of embryos for research purposes.

With respect to parthenogenesis, James McCartney speculates that if it was used successfully to create *in vitro* embryos, many of the ethical concerns associated with creating *in vitro* embryos specifically for research would be addressed. In his view, there would be minimal ethical concerns because the embryo would at no time be capable of developing into a human being.[272]

4.7.3 Discussion

Under the AHR Act, scientists are able to use supernumerary *in vitro* embryos that have been donated for research by the progenitors.[273] Individuals or couples who create *in vitro* embryos for reproductive purposes usually have a few frozen embryos remaining once their family is complete. The disposition options for the progenitors of these supernumerary embryos are: (1) donation to others for reproductive purposes, (2) donation for research purposes, and (3) destruction.

The difference between supernumerary *in vitro* embryos donated for research and *in vitro* embryos created through fertilization solely for research purposes is that the donated embryos were originally intended for reproduction. In all other aspects, supernumerary embryos, embryos created for research, and embryos created for reproduction are the same. It is likely that all three categories of *in vitro* embryos would theoretically have the same potential for human life. They have all been created through the union of a sperm and an egg resulting in a "unique" entity. Commentators have suggested that when the nucleus of the sperm and the egg unite, the genes combine to create a unique individual with an "open genetic future." [274]

Should research on the in vitro embryo be prohibited because of its potential for life?

Professor Robertson suggests that given the increased scientific knowledge regarding the various stages of pre-viable human life, it may be time for society to reassess the basis for differing viewpoints respecting the status of an *in vitro* embryo.[275] Until the *in vitro* embryo has been transferred into a woman's uterus, has successfully implanted into the uterine wall, and has developed to the point at which it would be viable outside its mother's body, it is difficult to assess the *in vitro* embryo's potential for human life. The early embryo lacks sentience and cognition, and is not an individual until after implantation and further development. The potential to become a person does not mean that the *in vitro* embryo is a person with legal rights.

---

[267] *Ibid.*

[268] *Ibid.*

[269] *Supra* note 27.

[270] *Ibid.* at 7.

[271] *Ibid.*

[272] *Ibid.*

[273] The term "progenitor" means the ancestor or genetic parent (Concise Oxford Dictionary, 10th Ed.).

[274] The phrase "open genetic future" refers to the potential of the human being with a unique DNA, resulting from the combination of DNA from a sperm and the DNA from an ovum, to be shaped by his or her environment.

[275] *Supra* note 256 at 2.

Scientific research has revealed that not every *in vitro* or *in utero* embryo has the potential to develop into a human being. A significant percentage of embryos have a genetic composition such that they could neither implant in the uterine wall nor develop once implanted. Even in sexual reproduction, a large number of fertilized eggs are aborted spontaneously, and some believe that "debrait is morally unconvincing to claim absolute inviolability for an organism with which nature itself is so prodigal."[276]

The potential for human life may not be the most rational basis on which to prevent the creation of *in vitro* embryos solely for research purposes, since it is difficult to assess and all three types of embryos discussed above arguably have the same potential for human life.

Is there a difference between those embryos created through in vitro fertilization and those embryos created through therapeutic cloning?

There may be important differences between embryos created through fertilization (the union of a sperm and an egg) and embryos created by therapeutic cloning. Many persons consider the therapeutically cloned *in vitro* embryo to be a copy of another person (the nucleus donor). One could argue that such embryos are not unique creations with an open genetic future, but rather are copies of existing persons destined to share the same genetic characteristics as those of the nucleus donor.

On the other hand, the therapeutically cloned embryo contains DNA from the nucleus donor and mitochondria DNA from the female egg donor, and thus it is not an exact copy of the nucleus donor. One could argue that the therapeutically cloned *in vitro* embryo is also a unique individual with an open genetic future.

With respect to the potential for human life, it is difficult to predict the therapeutically cloned embryo's potential for human life since no one has successfully used such an embryo for reproduction purposes. However, if the difficulties of successfully creating a cloned ewe are attributable to the cloned embryo's potential for life, it would be possible to conclude that the cloned human embryo possesses minimal potential to develop into a healthy human being.

Some individuals may argue that these fundamental differences make it less ethically and morally troubling to create embryos by therapeutic cloning solely for research purposes. However, other individuals may be concerned that creating an entity with potential for human life, however small, as a means to an end and not as an end in and of itself, could diminish society's respect for the sanctity of human life.

In addition to creating embryos through cloning, scientists may soon be able to create *in vitro* embryos solely for research purposes through parthenogenesis. The use of these embryos in research might be significantly less controversial.

In vitro embryos created through parthenogenesis are derived from an unfertilized human egg and are only able to develop to a certain point before they perish naturally. In addition, these embryos only have the genetic material of the female and thus are at no time capable of developing into a human being, i.e., they do not have the potential for human life. In order to create such an embryo, however, a woman must donate one of her ovum to research. Although perhaps not as controversial as the donation of an *in vitro* embryo for research, the use of a human egg in this way might still raise moral and ethical concerns.

For some individuals, the creation of an *in vitro* embryo by whatever method solely for research purposes raises issues of ethics and morality and displays a lack of respect for the sanctity of human life. The embryo can be viewed as part of the human community. An embryo created solely for research is arguably created as a means to an end, rather than an end in and of itself. For others, however, the donation to research of potentially viable supernumerary *in vitro* embryos, originally created for reproductive purposes, may be even more ethically troubling.

These concerns must be weighed and balanced with equally broad ethical and moral societal concerns related to progress in the fields of scientific and medical research. If research using *in vitro* embryos shows promises of producing medical cures and therapies for existing human beings suffering with debilitating and life-threatening diseases, are there not broad moral and ethical concerns raised if such research is prohibited?

---

[276] Royal College of Obstetricians and Gynaecologists. *Report of the RCOG Ethics Committee on In Vitro Fertilisation and Embryo Replacement or Transfer* (London: RCOG, 1983).

4.7.4 Conclusion

All embryos created through fertilization arguably have some potential for human life, even if science has demonstrated that such potential is less than originally believed. These *in vitro* embryos could be considered as unique entities with open genetic futures. The same cannot be said for those *in vitro* embryos created through therapeutic cloning and parthenogenesis since no one has successfully used them in reproduction. Based on animal research, they likely have less potential for human life than *in vitro* embryos created through fertilization. Cloned embryos may be considered by some to be mere copies of existing human beings, and thus would not be thought to possess a unique genetic makeup.

With respect to purpose, the *in vitro* embryo created through therapeutic cloning, embryo splitting or parthenogenesis is created solely for research purposes, with the intent of destroying it prior to the fourteenth day of development. These *in vitro* embryos have been created solely as a means to an end. On the other hand, *in vitro* embryos created for reproductive purposes were intended to develop into human beings. Once they become supernumerary, they become a proper subject of research.

It remains to be determined whether the differences discussed above would affect an embryo's moral status. Embryos created by cloning, splitting or parthenogenesis may be so fundamentally different, e.g. lack the potential for life, that concerns regarding their use in research would be minimized. For some individuals, however, the differences would not affect the moral status of an embryo which is derived from the fact that embryos are part of the human community. However, if scientists develop life-saving cures and therapies from research using the human embryo, society may be faced with choosing between the morality of research on an embryo and the morality of denying access to medical treatment.

4.8 Conclusion

Biotechnology is the result of scientific research. Without the freedom to ponder, opine, and experiment, scientists would not be able to research. This chapter examined the question of whether scientists have a human right to undertake scientific research. There are international and regional human rights instruments that link the principle of scientific freedom to human flourishing, and some of these instruments oblige State Parties to ensure that researchers have such freedom.

However, freedom to research, like any other human right, is not absolute. International and regional instruments note that freedom to research can be legitimately restricted by the state in those circumstances where other interests, such as public health, safety, morals, or ethics are implicated. The *Charter* guarantees freedom of thought, belief, opinion and expression in section 2(b). The Supreme Court of Canada has interpreted this continuum of freedoms broadly. The state can limit these freedoms but must be able to justify any restrictions under section 1 of the *Charter* as a reasonable limit prescribed by law in a free and democratic society.

Based on the existing jurisprudence, it is likely that scientific research would be found by the courts to fall within thought, belief, opinion and expression and thus would be protected by section 2(b). Although the experiment portion of scientific research is physical conduct, the Supreme Court has specifically noted that conduct that conveys or attempts to convey a message will be protected. The state would have an opportunity under section 1 to justify any restriction on scientific research and if successful, the restriction would be found to be constitutionally valid. There is no jurisprudence respecting a *Charter* right to undertake research and as such, this issue represents a novel area requiring future judicial interpretation.

It may be that there is a broad human right to enjoy the benefits and applications of scientific progress. Such a right might be relied on to argue that individuals have a right to access life-saving medical or scientific technology without state interference. A state restriction on access to such technologies, backed by penal sanction, would engage a person's rights under section 7 of the *Charter*, specifically the liberty and security of the person interests.

The final issue discussed was whether *in vitro* embryos created through different processes and for different purposes can be assigned different status. Embryos created through parthenogenesis are currently considered not to have the potential for human life. One could argue that these embryos should be assigned a lesser status than *in vitro* embryos created for reproduction purposes through the union of a sperm and an egg. If that was the case, the creation of *in vitro* embryos through parthenogenesis solely for research purposes would not likely raise ethical or moral concerns in society. On the other hand, the embryo may derive its status from the fact that it is part of the human community and as such, creation solely for research could not be justified. As biotechnology advances, society may have to choose between the creation and use of embryos solely for research, and the access of persons suffering with serious diseases and disorders to scientific cures and therapies derived from such embryos.

Government of Canada Gouvernement du Canada

A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 5

Human Rights Issues Related to Genetic Information and Privacy

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 5

Table of Contents

5.1 Introduction 5–1

5.2 The Science 5–2

5.3 Obtaining Genetic Information: Methods of Genetic Testing 5–2

- 5.3.1 DNA Testing 5–2
- 5.3.2 Indirect Genetic Testing 5–2
- 5.3.3 Family History 5–3

5.4 Comparative Legal Approaches to Genetic Information 5–3

5.5 Canadian Context 5–3

5.6 Issue 1: Discrimination 5–4

- 5.6.1 The International Context 5–4
- 5.6.2 The Comparative Context 5–4
- 5.6.3 The Canadian Context 5–5
- 5.6.4 Issues Arising in the Employment Context 5–7
- 5.6.5 Issues Arising in the Insurance Context 5–7
- 5.6.6 Issues Arising in Other Contexts 5–8
- 5.6.7 Conclusion 5–9

5.7 Issue 2: Privacy 5–9

- 5.7.1 The International Context 5–9
- 5.7.2 The Comparative Context 5–10
- 5.7.3 The Canadian Context84 5–10

5.8 Issues Arising with the "Right" to Know/Not Know 5–13

- 5.8.1 The International Context 5–14
- 5.8.2 The Comparative Context 5–14
- 5.8.3 The Canadian Context 5–15
- 5.8.4 Conclusion 5–16

5.9 Issues Arising Around Confidentiality 5–16

- 5.9.1 Conclusion 5–17

5.10 Gaps in the Human Rights Framework 5–17

5.11 Conclusion 5–18

Chapter 5

Human Rights Issues Related to Genetic Information and Privacy

Matthew Taylor

5.1 Introduction

The rapid and ongoing scientific advancement in the area of genetic information brings with it a complex set of legal, social and policy issues. Genetic information is a broadly understood concept that encompasses various elements, including information obtained through genetic research, as well as information related to family health history.[1] Genetic information can be ascertained through a variety of sources and can serve many useful purposes, some of which include:

- determining paternity;
- assisting in making reproductive choices and decisions relating to reproduction generally; and
- assisting in predicting, diagnosing, treating and preventing health conditions.[2]

Most importantly, genetic information about an individual is personal information.[3] It can, moreover, encompass aspects of information that tend to be highly sensitive in nature. This chapter will highlight some of the major legal and human rights issues that relate to genetic information. In particular, this chapter will canvass two significant areas: discrimination and privacy.

Within the context of discrimination, specific attention will be paid to the areas of employment and insurance. The discussion of privacy will focus on whether or not an individual has the right to know or not know their genetic information or that of a close family member. Further, issues relating to confidentiality of results of genetic testing will be examined.

In discussing these issues, this chapter will, for the most part, summarize the work done by the Genetic Information and Privacy Inter-departmental Working Group ("WG").

The WG was created in the fall of 2001 and has identified many challenges associated with genetic information. The WG has developed a national strategy designed to enhance privacy protection and freedom from discrimination on the basis of genetic information. The strategy is also geared towards providing individuals the ability to benefit from genetic research and health innovation. One way the WG is implementing this strategy is by looking at the existing legislative and policy frameworks dealing with privacy and discrimination with a view to strengthening these mechanisms in a way that deals with the issues posed by genetic information.

The issues of privacy and discrimination on the basis of genetic information will be analyzed within the domestic and international frameworks, including the approach of other jurisdictions. Where possible, gaps in the Canadian framework will be identified.

---

[1] See T. Lemmens and L. Austin, "Of Volume, Depth and Speed: The Challenges of Genetic Information" (February 2001) [unpublished], prepared for the Canadian Biotechnology Advisory Committee.

[2] E. Oscapella, "Genetics, Privacy and Discrimination: A Survey Prepared for the Canadian Biotechnology Advisory Committee" (31 October 2000) [unpublished] at 8.

[3] E. Oscapella, "Genetic Testing in Employment: A Review of Legislation and Policy Issues" (3 January 2003) [unpublished] at 11.

5.2 The Science

The nuclei of all human cells, except sperm and egg cells, contain 23 pairs of chromosomes (46 in total – 23 from each parent), which are composed of deoxyribonucleic acid ("DNA").[4] Essentially, DNA is the carrier of the genetic instructions for making living organisms.[5] Each human cell contains thousands of genes, which are short sections of DNA, that act either together or independently to produce proteins.[6] These proteins are essential for the following processes: providing cell structures, producing hormones, and transporting substances throughout the body.[7] When proteins are not synthesized properly, it may be assumed that the genetic information that instructs its creation is at fault.[8] Thus, understanding the genetic anomaly behind the improperly created protein is an important step in understanding how to devise treatments for those persons with genetic conditions.

An individual may have a genetic mutation that results in a particular disease or disorder. The most commonly tested for single gene disorders are cystic fibrosis, beta-thalassaemia and Huntington's disease. As scientific knowledge regarding the human genome increases, the number of diseases, such as heart disease and certain cancers, for which a predisposition can be determined through genetic testing, will also increase.[9]

It is important to note that, at this point in time, genetic tests only reveal whether an individual is likely to develop a genetic disease or disorder but not the degree to which the condition will affect the individual.[10]

5.3 Obtaining Genetic Information: Methods of Genetic Testing

Genetic information can be obtained through different means and for different purposes. Information can be obtained through DNA testing, indirect genetic testing and through family medical history.[11] In addition to the various methods that can be utilized to obtain genetic information, genetic testing can be employed at different stages in one's lifetime. For instance, testing can be done pre-conception on sperm or ova; *in vitro*, on an embryo created outside the body; and pre-natal, on the fœtus. It can also be done at the time of birth in an effort to reduce the progression of diseases that require early detection and treatment. Finally, genetic testing can be done at any other point in time to assess the likelihood of potential genetic disorders.[12]

5.3.1 DNA Testing

Through the analysis of DNA, scientists have been able to assess whether individuals contain genetic mutations known to be indicators of various diseases, such as Alzheimer's disease, cystic fibrosis, sickle cell anaemia and Tay-Sachs disease.[13] DNA testing provides scientists the information that enables them to physically map different genes, showing their size, order and numbering.[14] DNA testing is becoming more common, and is, perhaps, one of the more sophisticated ways of obtaining genetic information. DNA testing has improved greatly over the past few decades as a result of incredible advances in scientific technology.

5.3.2 Indirect Genetic Testing

Another method employed to obtain genetic information is through indirect genetic testing. One type of indirect genetic testing is through analyzing bodily substances such as urine, blood or other bodily fluids. It can also be accomplished through the identification of visible characteristics caused by genetic conditions.[15] For example a diagnosis of spina bifida, a birth defect where the spine does not form completely, is a form of indirect genetic testing because the visible characteristics associated with this illness are known to be caused by genetic anomalies. A further method of obtaining genetic information through indirect testing involves chromosomal analysis where abnormalities can be seen. One example of chromosomal analysis is amniocentesis.[16]

---

[4] S.A. Sherwood, "Don't Hate Me Because I'm Beautiful… and Intelligent… and Athletic: Constitutional Issues in Genetic Enhancement and the Appropriate Legal Analysis" (Summer, 2001) 11 Health Matrix: Journal of Law-Medicine 633 at 635.

[5] Ontario: Ministry of Health, "Genetic, Testing and Gene Patenting: Charting New Territory in Health Care" online: http://www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf accessed: 09 January 2004 11:20AM.

[6] S.A. Sherwood, *supra* note 4 at 635.

[7] Online: http://www.ontariogenomics.ca/gc/ogi/aboutGenomics whatIsGenomicsOGI.asp?l=e accessed 08 January 2004 9:37AM.

[8] *Ibid.*

[9] Kay Chung, *Designer Myths: the Science, Law and Ethics of Preimplantation Genetic Diagnosis* (London: Progress Educational Trust, 1999) at 10-11.

[10] Maha F. Munayyer, Genetic Testing and Germ-Line Manipulation: Constructing a New Language for International Human Rights (1997) 12 Am. U.J. Int'l L. & Pol'y 687 at 3 (Lexis Nexis).

[11] T. Lemmens and L. Austin, *supra* note 1 at 6-7.

[12] *Ibid.* at 8-9.

[13] *Ibid.* at 6-7.

[14] *Ibid.* at 6.

[15] *Ibid.* at 7.

5.3.3 Family History

One of the more traditional ways to ascertain genetic information about an individual is through the taking of a detailed family medical history. It is well known that certain diseases are hereditary and that individuals within some families are more susceptible to a particular disease given that close family members have the disease and that the family shares certain genetic characteristics. Examples of conditions that have a genetic basis include breast cancer and Huntington's disease.[17] A family medical history is one source of genetic information that can lead to the identification of "at risk families".[18]

5.4 Comparative Legal Approaches to Genetic Information

The legal protection granted to genetic information varies from jurisdiction to jurisdiction. This variance is partially a result of the different ways countries have conceptualized genetic information. For instance, in Australia genetic information is encompassed by the larger concept of health information.[19] This is also the case in Iceland, although in Iceland health information is further subsumed in the broader concept of personal data.[20] In the United Kingdom ("U.K."), genetic information is considered "sensitive personal data".[21] Finally, in India there is no general data-protection legislation, however the government protects privacy rights during the course of biomedical research through measures provided by the Department of Biotechnology.[22]

5.5 Canadian Context

Genetic information is afforded protection through legislation and the common law in Canada. Canada's protection of genetic information varies depending on which level of government or jurisdiction is engaged, as well as the particular legislation involved. "Genetic information" is not specifically defined in many of the pieces of legislation that nonetheless may protect the rights of individuals from invasion of privacy and discrimination on the basis of genetic information. In other pieces of legislation, genetic information is defined.

Protection of personal information occurs through a variety of mechanisms under the legal frameworks dealing with either privacy or discrimination. Under the privacy framework, genetic information is afforded some legal protection by the *Canadian Charter of Rights and Freedoms*[23] (the "*Charter*"), the federal *Privacy Act*,[24] the federal *Personal Information Protection and Electronic Documents Act*[25] ("*PIPEDA*") and provincial[26] privacy and freedom of information legislation.

The *Charter* protects against state incursions into a person's reasonable expectation of privacy. The *Charter*'s application encompasses all actions and laws of the government, although it does not generally apply to actions of private actors.

Neither the *Privacy Act* nor *PIPEDA* specifically identifies "genetic information". Rather, they apply to "personal information" which arguably would include genetic information. Some of the provincial statutes are more explicit in extending protection to genetic information by including "inheritable characteristics" or "genetic information" in the definition of personal information.[27]

---

[16] *Ibid.*

[17] *Ibid.* at 8.

[18] *Ibid.*

[19] M. Letendre, C. Sallée et al., "Genetic Privacy: A Comparative Approach" (14 March 2003) [unpublished] at 9.

[20] *Ibid.* at 15.

[21] *Ibid.* at 12.

[22] *Ibid.* at 16-17.

[23] Enacted as Schedule B to the *Canada Act 1982* (U.K.) 1982, c. 11 which came into force 17 April 1982.

[24] R.S.C. 1985, c. P-21.

[25] S.C. 2000, c.5.

[26] In this paper, the words "province" and "provincial" include the Canadian territories.

[27] See Alberta's *Freedom of Information and Protection of Privacy Act*, R.S.A. 2000, c. F-25; Manitoba's *Freedom of Information and Protection of Privacy Act*, C.C.S.M. c. F175; Nova Scotia's *Freedom of Information and Protection of Privacy Act*, S.N.S. 1993, c. 5; Yukon's *Access to Information and Protection of Privacy Act*, R.S.Y. 2002, c. 1; and Northwest Territories' *Access to Information and Protection of Privacy Act*, S.N.W.T. 1994, c. 20.

Under the discrimination framework, protection can be found in Canadian human rights legislation. For instance, the federal *Canadian Human Rights Act*[28] and the corresponding provincial human rights statutes prevent discrimination against individuals in the area of employment and the provision of various services. The discussion that follows will explore whether or not individuals may be protected from discrimination on the basis of genetic information under the current legal framework in Canada.

5.6 Issue 1: Discrimination

As discussed above, advances in genetic research allow scientists to identify susceptibilities that individuals may have to a variety of diseases thus providing an opportunity to predict an individual's predisposition to certain conditions. These scientific developments provide the possibility for treatment to either decrease the severity of or to prevent possible disorders from manifesting, thereby providing hope to individuals and families who are genetically predisposed to disease.

However, obtaining information in advance with respect to an individual's risk of developing a genetic disorder could lead to discrimination in a variety of ways. For instance, insurance providers may refuse to insure persons who are predisposed to a particular disease. Similarly, predisposed individuals may find it difficult to obtain a job. In industries where employers often arrange for private health benefits for their employees there may be reluctance amongst employers to hire or retain employees who are genetically at risk of developing a debilitating illness which would prevent them from returning to work. Employers may simply refuse to hire these individuals on the basis of this risk and potential costs to their health plan. Even if employment is found, employers may assign individuals to certain positions based on perceived health risks or, alternatively, limit that individual's opportunities within the workplace. Other areas where there is a risk that genetic information can be used to discriminate include allocation of health resources, immigration screening and custody determination in family law matters.

This section will begin with a brief overview of the international and comparative frameworks relating to the area of genetic information and discrimination. It will then review the principles informing the Canadian legal approach to discrimination. Finally, it will turn to an analysis of issues that arise in the case of discrimination based on genetic information within the employment and insurance contexts.

5.6.1 The International Context

With respect to international law, there are few references to genetic information and discrimination. However, work has recently been undertaken to address the impact of advances in genetics. For instance, the 1997 UNESCO *Declaration on the Human Genome and Human Rights* encourages countries to prohibit discrimination based on genetic information.[29] The *Declaration*, which was adopted on 11 November 1997, recognizes the right of everyone to respect for their dignity and human rights regardless of their genetic characteristics.[30] The following year, it was endorsed by the United Nations General Assembly.[31] Similar efforts have been made in Europe with the 1997 *Convention on Human Rights and Biomedicine*,[32] which prohibits all forms of discrimination based upon genetic information. Canada is not a party to the European Convention and is therefore not bound by it. Finally, on 16 October 2003 the UNESCO *International Declaration on Human Genetic Data* was adopted unanimously at the 32nd session of the General Conference.[33] The *Declaration* aims to "ensure the respect of human dignity and protection of human rights in the collection, processing, use and storage of human genetic data."[34]

5.6.2 The Comparative Context

Several countries have dealt with the issue of discrimination on the basis of genetic information. For example, France has had legislation for some time prohibiting discrimination on the basis of genetic characteristics.[35]

---

[28] R.S.C. 1985, c. H-6.

[29] *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, 29th Sess., (adopted unanimously and by acclamation). Under international law, a Declaration is not binding on state parties but rather a sign of support for the principles contained therein. For more information see chapter 1 *supra*.

[30] E. Oscapella, *supra* note 2 at 19.

[31] GA Res. AIRES/53/152, UNGAOR, 53d Sess., (1998).

[32] ETS No. 164.

[33] *International Declaration on Human Genetic Data*, 16 October 2003, UNESCO, 32nd Sess., (adopted unanimously and by acclamation).

[34] *Ibid.*

[35] See article 16-13 of the *Civil Code*, Book 1/Title1/Chapter 2.

In the United States ("U.S."), a number of states have enacted legislation dealing with the use of genetic information in the workplace and, in 2000, an executive order was signed by President Bill Clinton preventing every federal department from using genetic information in any hiring or promotion action.[36] Further, on 14 October 2003, the U.S. Senate passed Bill S 1053 prohibiting discrimination on the basis of genetic information in the areas of employment and health insurance.[37]

In Australia, the Law Reform Commission is proposing to add discrimination on the grounds of genetic status to its anti-discrimination legislation. Genetic information is also being addressed through a variety of legislative regimes in other countries including Iceland, the U.K. and India.

5.6.3 The Canadian Context

Understanding Discrimination

The Supreme Court of Canada's ("SCC") 1999 decision in *Law v. Canada*[38] discussed the difficulty which exists in trying to define the concept of "discrimination" given its abstract nature.[39] What is clear, however, is the importance of focussing on the realization of human dignity, the disregard of which leads to discrimination. In this regard, the Court noted:

> It may be said that the purpose of s. 15(1) is to prevent the violation of essential human dignity and freedom through the imposition of disadvantage, stereotyping, or political or social prejudice, and to promote a society in which all persons enjoy equal recognition at law as human beings or as members of Canadian society, equally capable and equally deserving of concern, respect and consideration. Legislation which effects differential treatment between individuals or groups will violate this fundamental purpose where those who are subject to differential treatment fall within one or more enumerated or analogous grounds, and where the differential treatment reflects the stereotypical application of presumed group or personal characteristics, or otherwise has the effect of perpetuating or promoting the view that the individual is less capable, or less worthy of recognition or value as a human being or as a member of Canadian society.[40]

In essence, discrimination results when individuals or groups are unfairly disadvantaged by a government measure, based on their personal characteristics, in a manner that offends their human dignity. In Canada, complaints about discriminatory conduct can be addressed through different mechanisms. The *Charter*, as well as federal and provincial human rights legislation, provides individuals protection from discriminatory conduct.

The *Charter*

Section 15 of the *Charter*, the equality provision, provides every individual protection from discrimination. It reads:

> 15 (1) Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.
>
> (2) Subsection (1) does not preclude any law, program or activity that has as its object the amelioration of conditions of disadvantaged individuals or groups including those that are disadvantaged because of race, national or ethnic origin, colour, religion, sex, age or mental or physical disability.

The grounds set out in s. 15 of the *Charter* are not meant to be exhaustive. Rather, protection from discrimination based on personal characteristics includes both the enumerated grounds listed within the section, and analogous grounds.[41]

An individual's predisposition to a particular disease, evidenced through the analysis of their genetic information, could potentially be included under mental or physical disability and thus be afforded protection under s. 15 of the *Charter*. The SCC has had various opportunities to consider the notion of disability. The crux of these decisions recognizes that disability is not simply defined by reference to a biomedical condition, but also includes the societal response to those conditions.[42] The Court noted the following on disability in *Québec (Commission des droits de la personne et des droits de la jeunesse) v. Boisbriand (City)*:[43]

---

[36] E. Oscapella, *supra* note 2 at 13.

[37] Online: http://thomas.loc.gov (accessed 14 January 2004).

[38] [1999] 1 S.C.R. 497 (hereinafter "*Law*").

[39] *Ibid.* at para. 52.

[40] *Ibid.* at para. 51.

[41] The Supreme Court of Canada in *Corbiere* v. *Canada*, [1999] 2 S.C.R. 203 at para. 13 defined analogous grounds as those "characteristics that we cannot change or that the government has no legitimate interest in expecting us to change to receive equal treatment under the law." The Court has recognized a variety of analogous grounds including sexual orientation (See *Egan v. Canada*, [1995] 2 S.C.R. 513) and citizenship (See *Andrews v. Law Society of Upper Canada*, [1989] 1 S.C.R. 143).

> ... a "handicap" may be the result of a physical limitation, an ailment, a social construct, a perceived limitation or a combination of all these factors. Indeed, it is the combined effect of all these circumstances that determines whether the individual has a "handicap"...
>
> It is important to note that a "handicap" may exist even without proof of physical limitations or the presence of an ailment. The "handicap" may be actual or perceived and, because the emphasis is on the effects of the distinction, exclusion or preference rather than on the precise nature of the handicap, the cause and origin of the handicap are immaterial.[44]

Similarly, in *Granovsky v. Canada*,[45] the Court noted:

> The true focus of the s. 15(1) disability analysis is not on the impairment as such, nor even any associated functional limitations, but is on the problematic response of the state to either or both of these circumstances. It is the state action that stigmatizes the impairment, or which attributes false or exaggerated importance to the functional limitations (if any), or which fails to take into account the "large remedial component" [citation omitted] or "ameliorative purposes" [citation omitted] that creates the *legally relevant* human rights dimension to what might otherwise be a straightforward biomedical condition.[46] [emphasis in original]

The current jurisprudential approach to disability under s. 15 of the *Charter* may provide a legal mechanism to protect individuals from government discrimination on the basis of perceived disability due to genetic predisposition.

Human Rights Legislation

The *Canadian Human Rights Act*[47] protects individuals from discrimination in matters that come within the purview of the legislative authority of Parliament, such as banks and airlines.[48] The Act prohibits discrimination on the basis of disability, which is the most likely ground that would include and protect individuals whose genetic information indicates they are at risk of disease. The 2000 "La Forest Report," a major review of the *Canadian Human Rights Act*, recommended that the definition of disability under that Act be amended to include the predisposition to being disabled.[49] At present, the Act does not explicitly define disability to include predisposition to disability.

At the provincial level, legislation exists to protect individuals from discrimination based on disability (or handicap) within their respective spheres of competence. For instance, the *Ontario Human Rights Code*[50] prohibits discrimination in the areas of employment, accommodation and the provision of services.

Legislation in Ontario and Nova Scotia makes it clear that protection extends to cases of perceived disability. In Ontario, "because of handicap" means for the reason that the person is believed to have or have had any degree of physical disability, birth defect or illness. In Nova Scotia, physical disability or mental disability is defined to include perceived physical and mental disabilities.

Alberta, Saskatchewan, and Newfoundland define disability to include any degree of disability caused by a birth defect. This could lend itself to include a predisposition to a disability caused by a birth defect. Prince Edward Island defines a physical or mental handicap as a previous or existing disability caused by a birth defect. This definition could lead to a limited interpretation that includes a predisposition to disability. British Columbia and Manitoba have no definition of disability.

---

[42] N.M. Ries, "Discrimination, Disability and Privacy: Judicial Interpretations and Implications Regarding Use of Genetic Information" (March 2003) [unpublished] at 14.

[43] [2000] 1 S.C.R. 665 (hereinafter "*Boisbriand (City)*").

[44] *Ibid.* at para. 76.

[45] [2000] 1 S.C.R. 703 (hereinafter "*Granovsky*").

[46] *Ibid.* at para. 26.

[47] *Supra* note 28.

[48] *Ibid.* s. 2.

[49] Canada, Minister of Justice and the Attorney General of Canada, *Report of the Canadian Human Rights Act Review Panel* (Ottawa: Canadian Human Rights Act Review Panel, 2000) (Chair: The Honourable Gérard V. La Forest) (hereinafter "La Forest Report").

[50] R.S.O. 1990, c. H.19.

A majority of the provinces exempt providers of insurance that base an exclusion on reasonable or bone fide grounds because of disability.[51] As with federal legislation, the corresponding provincial human rights statutes prohibit discrimination on the basis of "disability" or "handicap". And like their federal counterpart, it is likely that this prohibition would encompass predispositions to disease or illness determined through the analysis of genetic information. It appears, however, that to date none of the provincial or territorial statutes explicitly define disability to include a predisposition to disease.

5.6.4 Issues Arising in the Employment Context

All human rights legislation in Canada prohibits discrimination in employment based on disability or handicap.[52] Additionally, the *Charter* regulates the conduct of the federal and provincial governments qua employer. If a genetic predisposition to disease falls within the purview of disability, individuals would have grounds under human rights legislation and the *Charter* to challenge discrimination. Having said this, under human rights legislation, an employer may refuse to hire an individual if they are able to establish a bona fide occupational requirement. If the employer can prove that a bona fide occupational requirement exists, then no discrimination is found under the legislation. The test for finding a bona fide occupational requirement has been articulated in two SCC decisions.[53]

Issues of discrimination on the basis of genetic information could potentially arise at various stages within the employment context. Genetic screening is a one-time testing of workers to determine individual susceptibility to existing workplace hazards or suitability to perform job functions.[54] An employer may be interested in utilizing genetic screening pre-employment, at the time of hiring, and post-hiring.[55] The use of such screening could lead to issues of discrimination in the workplace.

Offers or terms of employment tied to the genetic disposition of a particular individual may give rise to allegations of discrimination. However, the employer may be able to justify these requirements. If a potential or current employer seeks to limit opportunities within a workplace on the basis of genetic information obtained through genetic screening, the onus will be on the potential or current employer, once a *prima facie* case of discrimination has been made out, to show that such measures are bona fide occupational requirements.

Clearly, the possibility exists for genetic information-based employment discrimination. Some have suggested that employment discrimination based upon a predisposition or perceived predisposition would be prohibited under human rights legislation.[56] As noted above, the 2000 La Forest Report recommends amending the definition of disability under the *Canadian Human Rights Act* to clearly include predisposition to illness.[57] This recommendation would apply to matters falling within the sphere of federal jurisdiction. Provincial human rights legislation would not be affected by the implementation of such a recommendation. At present there remains no explicit prohibition against discrimination on the basis of predisposition to illness under federal or provincial legislation.

5.6.5 Issues Arising in the Insurance Context

Insurance is a contract between an insurer and an insured in which the insurer agrees to underwrite a risk in return for a payment from the insured.[58] Insurance companies assign a level of risk to individuals which determines whether an individual will be insured, and if so, at what cost. Insurance companies may exhibit greater reluctance to insure individuals who suffer from or are at a high risk of illness. Consequently, access to genetic information that discloses a predisposition to illness can play a significant role in the ability of these individuals to obtain insurance.

---

[51] Including British Columbia, New Brunswick, Newfoundland, Nova Scotia, Ontario, Saskatchewan, Prince Edward Island, Quebec and Yukon.

[52] N.M. Ries, *supra* note 42, at 18.

[53] *British Columbia (Public Service Employee Relations Commission) v. British Columbia Government and Service Employees' Union (B.C.G.S.E.U.)*, [1999] 3 S.C.R. 3 (hereinafter "*Meiorin*"), and *British Columbia (Superintendent of Motor Vehicles) v. British Columbia (Council of Human Rights)*, [1999] 3 S.C.R. 868 (hereinafter "*Grismer*"). In *Grismer*, the Court articulated the test for finding a bona fide occupational requirement at para. 20 as follows:
  (1) Is the discriminatory standard rationally connected to the function being performed?;
  (2) Did the defendant adopt the particular standard with an honest and good faith belief that it was necessary for the fulfillment of its purpose or goal?; and
  (3) Is the standard reasonably necessary for the defendant to accomplish its purpose or goal?

[54] THiiNC Health Inc., "Genetic Information: Domestic Health, Insurance, and Employment Sector Issues for the Federal Government. A Report for the Federal Working Group on Genetic Privacy and Information" (March 2001) [unpublished] at 52-53.

[55] *Ibid.* at 53.

[56] See E. Oscapella, *supra* note 3 at 26-27; N.M. Ries, *supra* note 42 at 15.

[57] *Supra* note 49 at recommendation 119.

[58] THiiNC Health Inc., *supra* note 54 at 43.

Genetic information has the potential to separate those who have access to insurance because of their genetic makeup from those who do not.[59] It might also result in those who are predisposed to genetic conditions being required to pay higher premiums due to the increased risk associated with insuring them. Human rights legislation does not prevent discrimination in the insurance context.[60] Accordingly, there exists a real possibility that the use of genetic information in this context will have a significant impact on the ability of individuals who are genetically predisposed to illness to obtain insurance.[61] Moreover, requiring genetic information to be disclosed to insurance companies may also have a chilling effect on advance diagnoses of medical conditions. Individuals may be disinclined to seek out genetic information about themselves if they would be required to disclose the information to insurance providers.

There are two questions that arise: (1) whether the insurance industry will require genetic information when assessing applications for insurance, and (2) whether individuals will be denied insurance on the basis of their genetic information. Current industry practices do not demonstrate an interest amongst insurance companies to use genetic testing as an underwriting tool.[62] It is important to note that insurance companies already have access to an individual's genetic information when they require the individual to provide a family medical history.

Insurance companies do request access to the results of any pre-existing personal genetic information.[63] This may change in the future as advances in technology make it both cost effective and easier for individuals to undergo genetic testing.[64] Currently, not enough information is known about the links between an individual's genes, lifestyle and future health. The use of genetic tests by the industry as a basis for decisions regarding insurance may be inappropriate.

In Canada, the insurance industry falls under provincial jurisdiction. In the common law provinces, the various statutes dealing with insurance are substantially similar as they are all drawn from the *1922 Uniform Insurance Act*. In Quebec, the only civil law province, the *Civil Code* creates a similar legal framework.

There is currently no legislation in Canada to specifically address the possibility of genetic discrimination in the context of private insurance contracts.[65] In addition, nothing currently exists to prevent genetic testing from being a prerequisite to obtaining private health or life insurance. Any legislation that regulates the insurance industry must be in compliance with the *Charter*.

5.6.6 Issues Arising in Other Contexts

As mentioned previously, discrimination based on genetic information could arise in a variety of other circumstances. For instance, genetic information could be used in the immigration law context in order to screen persons seeking to immigrate to Canada.

Some authors have suggested that there exists a possibility for discrimination in the health care sector as well.[66] Questions of what the government is willing to fund within the health care context may also give rise to issues of discrimination based upon genetic information.

In the family law context, questions respecting custody of, or the adoption of, children may also be influenced by the information obtained about parents through genetic testing.[67] Other potential areas of concern include military service and the ability to obtain financial services, such as access to credit.[68]

---

[59] E. Oscapella, *supra* note 2 at 25.

[60] *Ibid.* at 13.

[61] *Ibid.* at 25.

[62] THiiNC Health Inc., *supra* note 54 at 44.

[63] *Ibid.*

[64] *Ibid.*

[65] *Ibid.* at 49.

[66] N.M. Ries, *supra* note 42 at 21-22.

[67] N. Carnadin, "Genetic Information: The Domestic Legal Framework" (28 February 2003) [unpublished] at 68.

[68] See E. Oscapella, *supra* note 2 at 25.

5.6.7 Conclusion

In Canada, there appears to be no explicit statutory prohibition on discrimination based upon a predisposition to illness. Having said this, recent jurisprudence from the SCC supports the proposition that genetic predisposition would be caught under the rubric of disability.[69] These decisions emphasize that the concept of disability is not limited solely to biomedical conditions, but must also encompass societal perceptions and responses to such conditions. It has been recommended in the La Forest report that the definition of disability under federal human rights legislation be amended to include genetic predisposition to illness. While this recommendation arose during a review of the federal *Canadian Human Rights Act*, it could be extended to include provincial human rights legislation as well. This would extend protection from genetic discrimination to all Canadian jurisdictions and ensure consistency across them.

The use of genetic information in the areas of employment and insurance raises the possibility of discriminatory conduct. This risk extends to other areas including immigration, family law and access to health benefits. In this regard, the use of genetic information can threaten the basic human right of equality. In crafting an appropriate legal, social and policy response to these concerns, it is important that human rights principles are kept in mind.

5.7 Issue 2: Privacy

Privacy has been defined as "limited access to a person, the right of an individual to be left alone and the right to keep certain information from disclosure to other individuals."[70] Privacy encompasses both the liberty and intimacy interests of individuals.[71] There exist many concerns about safeguarding the privacy of genetic information, particularly as it touches on highly personal and sensitive information about individuals and their family members.[72] Ongoing developments in technology create new challenges to the protection of information, including the protection of genetic information.

The concept of privacy is closely linked to confidentiality. Conceptually, however, they can, if respected, protect an individual in different ways. As noted above, privacy is about an individual not being required to provide certain types of information about themselves to others. Confidentiality, on the other hand, may be said to involve the prevention of information known about a person from being further disclosed to a third party or utilized for purposes not authorized by the individual whose information is at issue. So while privacy interests are about information not being revealed by others, confidentiality prevents information, once revealed, from further unauthorized disclosure. Both serve to protect the liberty and integrity interests of the individual.

This section will review the privacy and confidentiality issues that arise within the context of genetic information. One specific issue that will be addressed is whether or not individuals have the "right" to know or not know the genetic information of close family members. The possibility of family members having a right to know conflicts with an individual's privacy interests, as well as their interest in having their genetic information kept confidential.

5.7.1 The International Context

The right to privacy and confidentiality is recognized in numerous international documents, both generally and in relation to genetic and health information. Article 17 of the *International Covenant on Civil and Political Rights* stipulates, "no one shall be subjected to arbitrary or unlawful interference with her or his privacy".[73] The UNESCO *Declaration on the Human Genome and Human Rights* mandates that genetic information associated with an identifiable person and stored for any purpose must be kept confidential.[74] Similarly, the UNESCO *International Declaration on Human Genetic Data* encourages states to ensure that the privacy of individuals and the confidentiality of their genetic information. This *Declaration* provides that genetic information should not be disclosed to third parties except for important public interest reasons.[75]

---

[69] *Boisbriand (City), supra* note 43; and *Granovsky, supra* note 45.

[70] M.A. Rothstein, "Genetic Privacy and Confidentiality: Why They Are So Hard to Protect" (1998) 26 *Journal of Law, Medicine & Ethics* 198.

[71] B.M. Knoppers, "Genetic Privacy: A Policy Approach" (15 April 2003) [unpublished] at 4.

[72] N.M. Ries, *supra* note 42 at 25.

[73] *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171, art. 17 (entered into force 23 March 1976).

[74] *Supra* note 29. See Article 7 of the Declaration.

[75] *Supra* note 33. See Article 14 of the Declaration.

Regional documents also consider the issue of the right to privacy. For instance, the *Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings*[76] states, "every one has the right to respect for private life in relation to information about his or her health". The 2000 *Charter of Fundamental Rights of the European Union* recognizes that genetic privacy is a fundamental right.[77]

5.7.2 The Comparative Context

Iceland has enacted legislation that treats genetic information as health information.[78] Iceland also stores personal genetic information in genetic data banks and its law presumes that this information has been stored by consent unless an individual has explicitly opted out. Essentially, Iceland's legislation authorizes the establishment of a centralised database of non-identifiable personal data to promote medical knowledge.[79]

Iceland's commodification of its "genetic resources" is not without controversy.[80] For one, the genetic database has been initiated by a commercial firm, in cooperation with the government, creating the possibility of a licensing system which allows for a license to be granted to only one party, thus creating a virtual monopoly.[81] Another concern raised has been the sufficiency of the measures taken to make the information non-identifiable thereby protecting the privacy of the individuals whose information is stored.[82] The commercialization is particularly controversial as it allows a private entity to profit from the personal genetic and medical histories of the Icelandic people.[83] Certainly, Iceland's model for protecting genetic information represents a unique approach compared with other states.

5.7.3 The Canadian Context[84]

In Canada, privacy is protected through a variety of mechanisms including constitutional law, federal and provincial legislation, and the common law. The *Charter* is an important legal safeguard for the protection of privacy in Canada. Again, however, the *Charter*'s applicability is limited generally to instances involving government action. Moreover, as will be demonstrated below, the *Charter*'s protection of privacy is predominantly limited to areas where there exists a "reasonable expectation of privacy."

The *Charter*

On its face, the *Charter* does not guarantee a right to privacy: rather, privacy interests are encompassed within the various rights specifically protected under the *Charter*, and in particular s. 8.[85] There is, however, a residual source of privacy protection found under s. 7. While the state can intrude on these rights by virtue of s. 1 of the *Charter*, stringent conditions must be met before this section will limit a constitutionally protected right.[86]

Section 8 of the *Charter* states: "[e]veryone has the right to be secure against unreasonable search or seizure." The protection afforded by s. 8 predominantly arises in the criminal context. The role that s. 8 plays is to protect against unjustified state intrusions on individuals' reasonable expectation of privacy.[87] In determining whether s. 8 will operate to protect a privacy interest, regard must be had to the object or information that is searched or seized.[88] A reasonable expectation of privacy, in relation to the object or information must be established in order for the s. 8 right to be triggered.[89] Depending on the context, expectations of privacy will vary. Numerous court decisions have discussed the protection of privacy under s. 8.

In *Canadian Aids Society v. Ontario*,[90] Wilson J., of the trial division, had opportunity to discuss the protection to be given to information obtained from blood samples that were voluntarily donated to the Red Cross. The Court held:

---

[76] *Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings*, 12 January 1998, E.T.S. No. 168 (Council of Europe).

[77] *Charter of Fundamental Rights of the European Union*, 18 December 2000, Official Journal of the European Communities C 364/1.

[78] An *Act on Protection of Individuals with Regard to the Processing of Personal Data No 77/2000*.

[79] M. Letendre, C. Sallée *et al.*, *supra* note 19 at 16.

[80] *Ibid.* at 6.

[81] L. Nelson, "The Icelandic Health Sector Database, Legal and Ethical Considerations" in T.A. Caufield and B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) 111 at 111.

[82] *Ibid.* at 121.

[83] *Ibid.* at 124.

[84] This section draws heavily upon the summary of N.M. Ries, *supra* note 42, and the author is indebted for this work, particularly the summary of the protections afforded by the *Charter*.

[85] N.M. Ries, *supra* note 42 at 25.

[86] E. Oscapella, *supra* note 2 at 10.

[87] *Hunter v. Southam Inc.*, [1984] 2 S.C.R. 145 at 160 (hereinafter "*Hunter*").

[88] N. Carnadin, *supra* note 67 at 12.

[89] *Ibid.*

[90] *Canadian Aids Society v. Ontario* (1995) 25 O.R. (3d) 388 (Gen. Div.), affirmed (1996), 31 O.R. (3d) 798 (C.A.), leave to appeal to S.C.C. refused (1997), 107 O.A.C. 80.

> The samples were given voluntarily. Consent, however, was not given to release the information in the blood to the public health authorities. There was a reasonable expectation of privacy when the donation was made. Donors would not have expected to be subjected to mandatory testing and public reporting ten years after making their donation.

The Ontario Court of Appeal affirmed this decision with little discussion.

In *R. v. Plant*,[91] the SCC noted:

> In fostering the underlying values of dignity, integrity and autonomy, it is fitting that s. 8 of the *Charter* should seek to protect a biographical core of personal information which individuals in a free and democratic society would wish to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individual.[92]

This passage tends to support the proposition that genetic information would be protected under the *Charter* as part of a person's "biographical core". The *Charter*'s protection would be triggered if the government committed an intrusion of the individual's reasonable expectation of privacy.

Similar language can be found in *R. v. Dyment*,[93] a case dealing with the collection of a blood sample by a physician who then turned the sample over to the police. In this decision, the SCC held that a patient has a privacy interest in his blood sample, an "intimately personal" substance.[94] Nonetheless, this information would only be protected by s. 8 of the *Charter* provided there was a reasonable expectation of privacy connected to the information.

In *Hunter*, the Court stated:

> The guarantee of security from unreasonable search and seizure only protects a reasonable expectation. This limitation on the right guaranteed by s. 8, whether it is expressed negatively as freedom from "unreasonable" search and seizure, or positively as an entitlement to a "reasonable" expectation of privacy, indicates that an assessment must be made as to whether in a particular situation the public's interest in being left alone by government must give way to the government's interest in intruding on the individual's privacy in order to advance its goals, notably those of law enforcement.[95]

Finally, in *Dyment*, the Court held:

> [g]rounded in man's physical and moral autonomy, privacy is essential for the well-being of the individual. For this reason alone, it is worthy of constitutional protection, but it also has profound significance for the public order. The restraints imposed on government to pry into the lives of citizens go to the essence of the democratic state.[96]

Section 7 of the *Charter* provides: "[e]veryone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice". Though not the primary source of privacy protection under the *Charter*, it does provide for some residual protection. The SCC has had the opportunity to discuss this section as it applies to the protection of privacy on various occasions.

In *R. v O'Connor*,[97] L'Heureux-Dube J. noted:

> Although it may appear trite to say so, I underline that when a private document or record is revealed and the reasonable expectation of privacy therein is thereby displaced, the invasion is not with respect to the particular document or record in question. Rather, it is an invasion of the *dignity* and self-worth of the individual, who enjoys the right to privacy as an essential aspect of his or her *liberty* in a free and democratic society. [emphasis added][98]

---

[91] [1993] 3 S.C.R. 281.
[92] *Ibid.* at 293.
[93] [1988] 2 S.C.R. 417.
[94] *Ibid.* at 432.
[95] *Hunter*, *supra* note 87 at 159-160.
[96] *Dyment*, *supra* note 93 at 427-428.
[97] [1995] 4 S.C.R. 411.
[98] *Ibid.* at 487.

The Court's discussion in *R. v. Mills*[99] is also informative:

> This Court has most often characterized the values engaged by privacy in terms of liberty, or the right to be left alone by the state… This interest in being left alone by the state includes the ability to control the dissemination of confidential information…
>
> These privacy concerns are at their strongest where aspects of one's individual identity are at stake, such as in the context of information "about one's lifestyle, intimate relations or political or religious opinion."[100]

The jurisprudence to date from the SCC demonstrates that while there is no explicit stand alone right to privacy under the *Charter*, privacy interests may be afforded protection under ss. 7 and 8. This is more readily the case with s. 8 protection against unreasonable search and seizure. It must be remembered, however, that the *Charter*'s protection extends to the actions of government and not private actors. Moreover, it must be demonstrated, for the s. 8 rights to be triggered, that the individual had a reasonable expectation of privacy. In addition, the jurisprudence discussed above and the corresponding rights articulated therein have arisen primarily in the criminal context. These considerations must be born in mind when looking at whether the protections afforded under the *Charter* would apply to genetic information in the non-criminal context.

Privacy Legislation

The collection, use, disclosure and retention of personal information by governments at the federal and provincial levels is regulated in Canada through privacy legislation. At the federal level, the *Privacy Act* provides the legislative framework which protects information in the hands of the federal government.[101] Personal information is defined under the *Act* as "information about an identifiable individual that is recorded in any form."[102] Examples of personal information include an individual's fingerprints and blood type, as well as their medical history. The scope of personal information protected by the Act has been interpreted broadly. In *Dagg v. Canada (Minister of Finance)*,[103] the SCC held:

> With these broad principles in mind, I will now consider whether the information requested by the appellant constitutes personal information under s. 3 of the *Privacy Act*. In its opening paragraph, the provision states that "personal information" means "information about an identifiable individual that is recorded in any form including, without restricting the generality of the foregoing". On a plain reading, this definition is undeniably expansive…the language of this section is 'deliberately broad' and 'entirely consistent with the great pains that have been taken to safeguard individual identity.' Its intent seems to be to capture any information about a specific person, subject only to specific exceptions.[104]

The SCC endorsed a broad approach to determine what constitutes personal information under the federal privacy legislation.[105] As a result, this approach might include genetic information.

The *Privacy Act* contains a Code of fair information practices that deals with the collection, retention, accuracy, use and disclosure of personal information by government institutions subject to the Act. The Code requires a government institution to:

- collect only the personal information that relates directly to an operating program or activity of the institution (s. 4);
- collect the personal information from the individual to whom it relates and inform the individual of the purposes of the information unless doing so might result in the collection of inaccurate information or defeat the purpose of prejudice the use for which the information is to be collected (s. 5);

---

[99] [1999] 3 S.C.R. 668.

[100] *Ibid.* at 721-722.

[101] The *Privacy Act* applies to government institutions listed in the Schedule.

[102] *Supra* note 24. See s. 3.

[103] [1997] 2 S.C.R. 403.

[104] *Ibid.* at para. 68 and 69. While this passage was expressed in the minority judgement, the majority expressly indicated agreement with this approach to the interpretation of the Act (at para. 1).

[105] This broad interpretation has since been confirmed by the SCC in *Lavigne v. Canada (Office of Commissioner of Official Languages)* (2002) SCC 53 and in *Canada (Information Commissioner) v. Canada (Commissioner of the RCMP)* (2003) SCC 8.

- retain the personal information that has been used for an administrative purpose long enough to allow the individual a reasonable opportunity to obtain access as specified in the regulations (s. 6);

- ensure the information that is used for an administrative purpose is as accurate, up-to-date and complete as possible (s. 6);

- unless the person consents otherwise, use the personal information for the purpose for which it was obtained, a consistent use, or for a purpose for which it can be disclosed under section 8 of the *Privacy Act* (s. 7);

- not disclose the personal information without the individual's consent unless one of the thirteen authorized disclosures under the *Privacy Act* applies (s. 8).

In addition to the *Privacy Act*, the federal *PIPEDA* establishes a national standard for data protection in all sectors and the extension of fair information practices to the private sector in Canada.[106] *PIPEDA* acknowledges that "health information" is personal information. As N. Carnadin describes:

> Section 2(1) defines "personal health information" for application in Part 1, the protection of personal information in the private sector. "Personal health information" concerns an individual, whether living or deceased, and includes information about the following: physical or mental health, the provision of health services as well as any information collected during the course of providing such services, the donation of any body part or bodily substance and any related information or testing as well as incidentally collected information. While *PIPEDA* does not use the term "genetic information" in the definition, it is clear that the comprehensive definition of personal health information includes protection for an individual's genetic information.[107]

PIPEDA requires organizations, unless one of the specific exceptions applies, to obtain the individual's consent when they collect, use or disclose personal information.

The *Assisted Human Reproduction Act*[108] ("AHR Act") contains a privacy scheme to protect personal health information, including genetic information, collected by fertility clinics and retained by the future AHR Agency. The AHR Act regulates the collection, retention, use, and disclosure of the personal health reporting information of sperm and ova donors, offspring created with donated gametes, and persons using donated gametes to create their families. In addition to the AHR Act, there are other federal laws that protect the privacy interests of individuals with respect to their genetic information.

In addition, the protection of privacy at the provincial level is accomplished through freedom of information and protection of privacy legislation. Each provincial statute contains a definition of personal information, although there is no specific reference to "genetic information,"[109] Despite this, the inclusion of information about an individual's blood type, fingerprints or inheritable characteristics, as well as information about a person's health, indicates that genetic information is included in the definition of personal information.[110]

Additionally, four provinces have created, through their provincial privacy legislation, a statutory tort of invasion of privacy.[111] The tort allows for an individual to seek legal redress, without proof of damage, when their privacy has been violated without their permission.[112] The tort addresses invasions of privacy committed in the provincial private sector.[113]

5.8 Issues Arising with the "Right" to Know/ Not Know

The idea that an individual has an interest in the results of her own genetic testing is obvious. Indeed, the very fact that she has consented to the test implies that she has the right to learn of the results. Arguably, the same result would hold in the case of an individual who was required to undergo genetic testing, for instance in the case where it was a pre-requisite for employment. Individuals who do not wish to know their genetic information should not be informed of the results. It is likely that requiring or mandating such testing would violate principles of individual autonomy.[114] Indeed, article 10 of the UNESCO International Declaration on Human Genetic Data states that individuals have the right to decide whether or not to be informed about the results of tests done for medical or scientific research purposes.[115]

---

[106] THiNC Health Inc., *supra* note 54 at 19. This Act sets out ground rules for how private-sector organizations may collect, use and disclose personal information in the course of their commercial activities (see section 4).

[107] N. Carnadin, *supra* note 67 at 22.

[108] *An Act Respecting Assisted Human Reproduction and Related Research*, Third Session, thirty-seventh Parliament, 52-53 Elizabeth II, 2004. Sections of the Act were proclaimed in force on April 22, 2004.

[109] N. Carnadin, *supra* note 67 at 28-29.

[110] *Ibid.* at 29.

[111] British Columbia, Saskatchewan, Manitoba and Newfoundland and Labrador have created this statutory tort.

[112] N. Carnadin, *supra* note 67 at 34.

[113] *Ibid.* at 39.

The notion of a "right" to know or not know becomes more contentious when close family members claim such a right with respect to the results of one member's genetic tests. Does an individual, whose close family member has been tested and found to have a predisposition to a genetic condition, have a legal "right" to be informed of that family member's test results? Further, does this answer change if one party is a minor?[116] Should an individual have a legal right or rather, would it be more appropriate to recognize, as a matter of public policy, that in certain instances an individual should be entitled to learn of the test results of a close family member?

5.8.1 The International Context

The issue of whether individuals should have access to the test results of close family members has garnered attention at the international level, and in other jurisdictions. The World Medical Association, as well as the Human Genome Organization and World Health Organization have suggested that a blood relative should only have access to an individual family member's genetic information under exceptional circumstances.[117] This information could only be disclosed under exceptional circumstances if the individual whose genetic information is sought is deceased.[118] Exceptional circumstances would include when the information could save the life of a relative or prevent serious harm.[119] The World Medical Organization has articulated this entitlement to be provided the genetic information of a family member as a "right" though strictly speaking the right is not legally enforceable. In this sense, the right articulates a moral imperative.

UNESCO's *International Declaration on Human Genetic Data* suggests that genetic data of an individual should not be disclosed or made accessible to third parties. However, it does recognize exceptions to this position. Article 14(b) reads:

> Human genetic data, human proteomic data and biological samples linked to an identifiable person should not be disclosed or made accessible to third parties, in particular, employers, insurance companies, educational institutions and the family, except for an important public interest reason in cases restrictively provided for by domestic law consistent with the international law of human rights or where the prior, free, informed and express consent of the person concerned has been obtained provided that such consent is in accordance with domestic law and the international law of human rights. The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected and the data should be treated as confidential.[120]

Thus disclosure of genetic data is only permitted if there has been prior informed consent or if there is an important public reason that is provided for by domestic law and is in accordance with the principles of international human rights. The Declaration does not create a "right" per se to the genetic information of close family members.

5.8.2 The Comparative Context

In Australia, the *National Health and Medical Research Council's National Statement* on Ethical Conduct in Research Involving Humans indicates that consent is required prior to disclosure of a family member's genetic information in all but two situations: (a) where the individual is dead, the information can be disclosed to the deceased's spouse or senior next-of-kin; and (b) when family members are at high risk of a serious disorder.[121] The Australian model demonstrates an approach to disclosure that is premised on policy rather than a legal right.

---

[114] E. Oscapella, *supra* note 2 at 21.

[115] *Supra* note 33. See article 10.

[116] E. Oscapella, *supra* note 2 at 22.

[117] See M. Letendre, C. Sallée *et al.*, *supra* note 19 at 74-75.

[118] *World Medical Association Declaration on the Rights of the Patient*. September/October 1981, WMA, 34th World Medical Assembly and amended by the 47th General Assembly. See article 8.

[119] M. Letendre, C. Sallée *et al.*, *supra* note 19 at 75.

[120] Article 14 (b), *supra* note 29.

The situation is more restricted in the U.K., where family access to genetic information about an individual is confidential, subject to the consent of the party whose genetic information is in question.[122] There is no explicit legislation providing a "right" to know. The Human Genetics Commission has indicated that in some instances family members may have a right to know, thus while there is no legal right to know there may be, in certain instances, a moral right.[123]

The U.S. has legislated in this area permitting disclosure of an individual's medical information without consent in limited situations including emergencies, when a provider is required by law to treat the individual, or when there are substantial communication barriers.[124] As such, access to genetic information is not guaranteed as of right.

In India, the Indian Council of Medical Research considers that family members hold a responsibility to inform those who are at high risk of disease.[125] Thus, in India the response is framed within a strictly ethical framework rather than a legal one.

Finally, in France discussion is underway to determine if it would be appropriate to pass a law to oblige a person to disclose their genetic information to their family circle once they have discovered a predisposition for disease.[126] Of all the jurisdictions discussed, this approach would be the most intrusive on an individual's right to privacy.

The international and comparative contexts demonstrate that there is no legal "right" to know the genetic information of a close family member. The approach taken by some jurisdictions of allowing limited access to genetic information of close family members appears to have been based on public policy reasons, rooted in moral imperatives, rather than legal rights. By and large, the presumption is that an individual's genetic information is to be kept private, with disclosure permitted as an exception in limited circumstances based public policy reasons, such as health and safety.

5.8.3 The Canadian Context

Canada does not provide individuals with the right to obtain the genetic information of a family member that may disclose a predisposition to illness. The legislative framework in Canada, which includes privacy legislation at all levels of government and the *Charter*, does not explicitly provide such a right. Similarly, there does not appear to be any case law addressing this issue.

The AHR Act permits the disclosure of health reporting information related to a donor of human reproductive material (or an *in vitro* embryo) to individuals using the donor's genetic material in an assisted human reproduction procedure, to any offspring conceived using the donor's genetic material or to descendants of the person so conceived. The AHR Act, however, does not permit the disclosure of the identity of the donor without his or her written consent.[127] Essentially, this provision creates a very limited statutory "right" to know for persons using or conceived with donated reproductive material or an *in vitro* embryo.

No Canadian jurisdiction has legislation imposing a legal obligation on individuals or health professionals to warn other family members of the results of genetic testing.[128] Mandating such an approach, strictly speaking, would not create a right for individuals to know, but rather it would impose a duty on individuals to disclose. Such a legal obligation would implicate s. 8 of the *Charter* and need to respect its dictates.

Legislation in Canada does not openly provide for a deontological approach to disclosure of personal information, nor does it support a "right" to know. Having said this, in some instances the legislation allows for disclosure as a matter of public policy.

---

[121] M. Letendre, C. Sallée *et al.*, *supra* note 19 at 76.

[122] *Ibid.* at 79.

[123] *Ibid.*

[124] *Standards for Privacy of Individually Identifiable Health Information*, Code of Federal Regulations, Title 45, CFR 164.506, Washington D.C., August 14, 2002, online: http://www.hhs.gov/generalweb/webapps/sitelink/site.asp?link_hhs=%20; http://www.cms.hhs.gov/hipaa/hipaa2/default.asp.

[125] M. Letendre & C. Sallée *supra* note 19 at 82-83.

[126] "MCCNE advice on the obligation to inform one's family of genetic risks" *Généethique* 46 (October 2003) online: http://www.geneethique.org. Accessed Jan. 2004

[127] *Supra* note 108 at s. 18(3).

[128] B.M. Knoppers, *supra* note 71 at 18.

For instance, Alberta's privacy legislation does contemplate disclosures of personal information if there are significant risks to the health and safety of the public, a particular group or an individual.[129] Similarly, Canada's *Privacy Act* permits disclosure when the public interest clearly outweighs any invasion of privacy that could result from such disclosure.[130] These examples do not provide for a right per se but rather mandate instances where, for public health reasons, disclosure of personal information is justified.

5.8.4 Conclusion

An individual currently has no legal right in Canada to be provided the genetic information of a close family member.[131] Further, an individual has no legal right in Canada to be informed that they may be genetically predisposed to illness simply because a close family member has been tested and shows susceptibility. Rather, it would appear that an individual's genetic information would be protected under constitutional and privacy law in Canada and that any unauthorized disclosure, even if it is to a close family member, may give rise to legal action.

The approach in other jurisdictions and internationally varies. The Australian and U.S. models tend to place the autonomy of the individual over that of the family members who claim a right to know. The proposed French approach places the right of family members to know as primary.

Clearly, human rights are engaged in this issue. At present, Canadian law has not dealt with the issue of the "right" to know. It remains to be seen whether this interest in knowing will develop into a free standing legal right.

5.9 Issues Arising Around Confidentiality

The implications arising from the discussion above are that, generally speaking, an individual has the right to have their genetic information kept confidential. No disclosure to family members is permitted. *Charter* jurisprudence concerning the right to privacy and the interests at stake, notably autonomy, liberty and dignity, suggests that individuals would have their rights to privacy and confidentiality protected if these rights are threatened by government action. Beyond this context, there are some additional safeguards in Canada to ensure that genetic information is kept private and confidential. The protections afforded arise in a variety of contexts including criminal law, healthcare and the collection or disclosure of information in the commercial context.

Under the *Criminal Code* (the "*Code*"),[132] DNA samples may be obtained by warrant for a number of designated offences. However, the Code also mandates that any DNA information obtained can only be used for the purposes of forensic DNA analysis.[133] Indeed, it is a criminal offence to use the DNA samples for any purpose other than those specified under the Code.[134]

In the context of healthcare, there is a common law duty of confidentiality. In *McInerney v. MacDonald*,[135] the SCC held that the special relationship between a doctor and his or her patient gives rise to the duty of the doctor to act with utmost good faith and loyalty and to hold information received from or about a patient in confidence.[136] This duty protects individuals from disclosure of their personal information for any unauthorized purposes, including genetic information, in all but exceptional circumstances.

There is no similar common law duty in the context of genetic information held by commercial organizations. In this respect federal, provincial and territorial legislation governing the collection, use and disclosure of personal health information applies. Part 1 of *PIPEDA* covers personal information, including personal health information, collected, used or disclosed by organizations within the private sector in the course of a commercial activity.

---

[129] Alberta *supra* note 27. See ss. 17(1) and 32(1).

[130] *Supra* note 24. See s. 8(2)(m)(i).

[131] B.M. Knoppers, *supra* note 71 at 19. Moreover there appears no legal duty to warn. Knoppers has suggested that at this time "any "duty" to warn at-risk family members be a matter of professional ethics and not [be] enshrined in legislation." She does note, however, that access to data of deceased family members should be legislated.

[132] R.S.C. 1985, c. C-46. The provisions dealing with DNA evidence are found at ss. 487.04- 487.092.

[133] *Ibid.* s. 487.08(1).

[134] *Ibid.* s. 487.08 (4).

[135] [1992] 2 S.C.R. 138.

[136] *Ibid.* at paras 20-22.

As of January 1, 2004, and relying on the federal government's trade and commerce power (found in s. 91(2) of the *Constitution Act, 1867*), *PIPEDA* applies to any organization engaged in the collection, use or disclosure of personal information, including health information, in the course of a commercial activity. If, however, the province has in place substantially similar legislation and it has been exempted by an Order of the Governor in Council, the application of *PIPEDA* to the collection, use, and disclosure of personal information within that province would be suspended. To date, only Quebec's *An Act Respecting the Protection of Personal Information in the Private Sector* has been deemed to be substantially similar pursuant to such an Order in Council (see Organizations in the Province of Quebec Exemption Order P.C. 2003-1842, 19 November, 2003). Therefore, only organizations within Quebec are exempt from the operation of *PIPEDA* as of January 1, 2004.

It should be noted that *PIPEDA*, while protecting the confidentiality interest of the individual pertaining to his or her personal health information, is limited to information obtained through "commercial activities."

5.9.1 Conclusion

In Canada, an individual's interest in the confidentiality of her or his personal information, including having one's genetic information kept confidential, is afforded protection under the *Charter*, the common law and other legislation. The protection of confidentiality afforded through the law makes the fulfillment of basic human rights possible, including the right to be protected from arbitrary interference with one's privacy. The WG has recommended, given the important role genomics plays in society, that policy development take place relating to the collection, handling, storage, use and management of federal government holdings of human genetic information.

5.10 Gaps in the Human Rights Framework

As noted above, the La Forest Report recommended that a genetic predisposition to a condition be explicitly afforded protection under Canadian human rights legislation. While it has been suggested above that recent jurisprudence in Canada may be sufficient to protect individuals from discrimination based on genetic information, there is no explicit protection against discrimination on the basis of genetic information. In this regard, a gap possibly exists in the law's ability to protect in the area of genetic information and discrimination.

Within the context of insurance, the use of genetic information by insurers to make decisions about providing insurance may impact on the ability of individuals to access health resources. Requiring individuals to provide insurance companies known genetic information may result in people refusing to undergo genetic testing. This, in turn, may adversely impact the health of individuals who might otherwise be able to receive treatment for their conditions. Genetic information and its use by the insurance industry can engage numerous human rights issues. As with the area of employment, there currently exists little jurisprudence dealing with this issue. It will be important to approach these areas with traditional human rights principles in mind, such as equality, security of the person and autonomy.

The potential for discrimination exists in a much broader sphere than the areas of employment and insurance. Some of the areas identified above include family, immigration and health law. The fact that so little attention has been paid to the topic of genetic information and its interplay with these areas of law also, by necessity, means that our understanding of the human rights issues in these areas remains largely rudimentary. Attention will be required in these areas in the future.

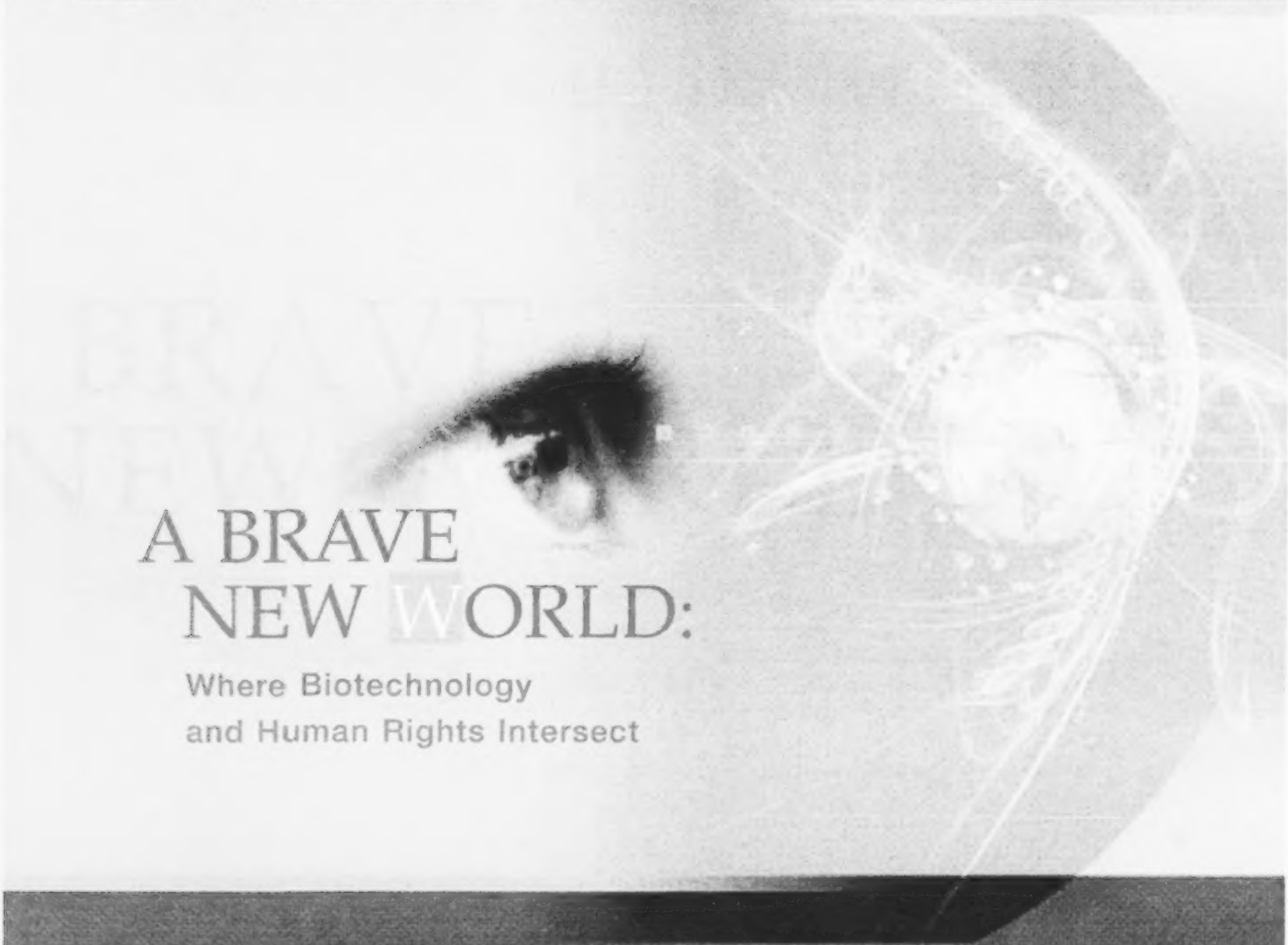
The issue of whether a close family member has the "right" to know the genetic information of another family member who learns that they are genetically predisposed to a condition has not been clearly articulated in Canadian law. This issue encompasses human rights concerns which may be addressed as a matter of public policy, or alternatively through a rights, or duty based approach.

5.11 Conclusion

The human rights issues relating to genetic information domestically and internationally will continue to arise in accordance with the advancement of our knowledge and subsequent use of genetic information in society. Clearly, our understanding of basic human rights such as the right to privacy, equality and security of the person will expand in recognition of the greater role that genetic information occupies in society. Additionally, other human rights as reflected in international documents, such as the right to benefit from scientific knowledge and the right to health will undoubtedly develop in accordance with our understanding of genetic information.

In large part, the rights evolution will develop in accordance with how societies choose to respond to the complex social and ethical issues that advancements in genomics will bring. At present, human rights discourse in this area is in its infancy. Yet, as this chapter has shown, there is recognition that the availability and use of genetic information does engage equality and privacy interests of individuals which may serve as useful starting points in the continuing development of this area.

Government of Canada Gouvernement du Canada



A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 6

Human Rights and Patenting

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 6

Table of Contents

6.1 Introduction 6–1

6.2 Background 6–1

6.3 Property Rights in the Human Body 6–8

6.3.1 The Principle of Human Dignity 6–9
6.3.3 Conclusion 6–12

6.4 Patents and Human Rights 6–12

6.4.1 International and Regional Instruments 6–12
6.4.2 The Law in Other Jurisdictions 6–19
6.4.3 Canada 6–30
6.4.4 Academic Literature and Commentary 6–37
6.4.5 Discussion 6–39

6.5 Does the Patenting of a Human *In Vitro* Embryo Raise any Human Rights Issues? 6–47

6.5.1 International and Regional Instruments 6–47
6.5.2 The Law in Other Jurisdictions 6–49
6.5.3 Canada 6–50
6.5.4 Discussion 6–51

6.6 Conclusion 6–52

Chapter 6

Human Rights and Patenting

Judy Hunter

6.1 Introduction

I should not like – under such circumstances, to be what I may call dispersed, a part of me here and a part of me there, but should wish to collect myself like a genteel person.[1]

A patent is a grant of monopoly rights by the state to the inventor (patentee) that allows him or her to capitalize on an invention by excluding others from making, using, selling or importing it for a limited period of time.[2] In exchange for this right, the patentee must publicly disclose a full description of the invention.

Patented inventions composed of non-living materials, such as wood or metal, rarely raise controversy with respect to subject matter. Beginning, however, in the 1980s, patent applications and grants over living materials, such as micro-organisms and human biological materials, began to attract attention and to raise ethical, moral and legal concerns.

More recently, advances in biotechnology and the completion of the Human Genome Project ("HGP") have combined to produce a dramatic rise in the number of patents issued over human materials, including human deoxyribonucleic acid ("DNA") sequences (genes). During the last decade, individuals and organizations began to voice concerns with the notion that human materials could be the subject of property rights that reside with a single owner (often a large corporation).[3]

This chapter examines the question of whether the issuing of patents in the area of biotechnology raises any human rights issues. It includes a discussion of property rights in the body and excised bodily materials, including a discussion of the common law and legislation. The chapter includes three hypothetical scenarios under which the issue of patenting and human rights is analyzed and discussed. It begins with a background section which provides a general discussion of patents and briefly explains the science and technology involved in the research and patenting of human bodily materials, including genes.

(The author wishes to thank Ray MacCallum, Laura Farquharson (both Counsel in the HRLS), Elisabeth Eid (General Counsel/Director HRLS), and Stan Benda (Counsel, Regulatory Law) for their review of drafts and their invaluable comments and suggestions. In addition, acknowledgements to Katherine van Heughten (Counsel, Health Canada Legal Services) and Robert Borland (Student-at-Law), for their preliminary research and work.)

6.2 Background

Patents

The state regulation of inventions through patents has a long and rather obscure history. Despite the uncertain origins, patents are considered to be the oldest form of intellectual property.[4] Some individuals believe that the issuing of patents began with a 1474 Venetian decree.[5] The British patent system can trace its roots to the "Monopoly System" begun during the reign of Queen Elizabeth I.[6]

---

[1] Charles Dickens, *Our Mutual Friend* (London: Penguin, 15th ed., 1984) at 127; Michelle Bourianoff, "Personalizing Personality: Toward a Property Right in Human Bodies" (1990) 69 Tex. L. Rev. 209.

[2] David Young et al., *Terrell on The Law of Patents*, 14th ed. (London: Sweet & Maxwell, 1994) at 1.

[3] Nuffield Council on Bioethics, *The ethics of patenting DNA: a discussion paper* (Nuffield Council on Bioethics: London, 2002) at 5.

[4] The Australian Law Reform Commission, *Intellectual Property Rights Over Genetic Materials and Genetic and Related Technologies* (Canberra: Department of Communications, Information Technology and the Arts, 2004) at 41.

In Canada, a statutorily based patent regime existed prior to Confederation in both Upper and Lower Canada. Canada's *Constitution Act, 1867* assigned exclusive legislative authority over patents to the federal Parliament.[7] Today, Canadian patents are granted by the Patent Commissioner in accordance with the *Patent Act* for any "new, useful, and unobvious… machines, products, processes, or improvements to existing technology."[8]

Each country grants patent rights according to its own rules or scheme enacted in its domestic legislation.[9] The World Intellectual Property Organization ("WIPO") works to promote the respect, use and protection of forms of intellectual property, such as patents. WIPO is an international organization that falls under the auspices of the United Nations. One of its objectives is to ensure administrative cooperation among the Member States. In addition, international trade organizations, such as the World Trade Organization ("WTO"), have attempted to introduce some common international rules through the TRIPS Agreement regarding intellectual property that must be adhered to by Member States.

It is important to emphasize that a patent does not give the patentee an automatic right to make, use, sell, or import an invention. Other domestic legislation may require approval of the invention before it may enter the marketplace. A patent grants to the patentee the right to exclude others from doing so.[10] It could be viewed as a reward by society for the inventor's inventiveness: it could be characterized as a "carefully crafted bargain" or social agreement between the inventor and society.[11] A patent regime arguably serves the public good by encouraging the invention and distribution of inventions, as well as the disclosure and furtherance of knowledge, in exchange for the patentee's right to exclude others from using, making, selling or importing the invention for a limited period of time, usually 20 years.[12]

Biotechnology and Patents

In the past, biochemical processes and methods of agriculture were generally refused patent protection because they were considered mere discoveries. However, the marriage of biology and technology produced methods or processes that were so different from what was considered "natural" that the courts began to uphold patents over them in the 1960s and 70s.[13]

Today, there are patent applications for entire animals, such as the Harvard oncomouse, entire plants, genes incorporated into either, as well as parts of the human body, which raise novel concerns. The continuing expansion of the biotechnology industry and the subsequent development of new products, using biological processes or living organisms, raise questions as to whether certain products or processes can or should be the subject-matter of a patent.

Critics of patents over human materials argue that instead of increasing knowledge and research in society, they often result in a negative impact on research, especially patents issued for human genes and cells. In their view, patents over extracted human materials may block the access of researchers to information and research materials, and thus impede research. Other commentators, however, point out that the concern with withholding new knowledge from society is not unique to patenting but also occurs when corporations protect their research and inventions by labelling them as "trade secrets."

---

[5] David Vaver, *Intellectual Property Law: Copyrights, Patents and Trade-Marks* (Concord, Ontario: Irwin Law, 1997) at 1.

[6] Young, *supra* note 2, at 2.

[7] *Constitution Act, 1867*, 30 & 31 Victoria, c. 3. (U.K.), s. 91(22).

[8] Vaver, *supra* note 5, at 113.

[9] Each country issues patent rights that are only valid in that jurisdiction. For example, a Canadian patent would not apply to activity in the United States.

[10] Sheldon W. Halpern, Craig Allen Nard and Kenneth L Port, *Fundamentals of United States Intellectual Property Law: Copyright, Patent, and Trademark* (The Hague: Kluwer Law International, 1999) at 252.

[11] *Bonito Boats*, 489 U.S. at 149 (United States Supreme Court); Cynthia Ho, "Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries" (2002) Hous. J. Health L. & Pol'y 107, at 113.

[12] E.R. Gold & T. A. Caulfield, "Human Genetic Inventions, Patenting and Human Rights" (Edmonton, Alberta, Health Law Institute, 2003) at 26.

[13] Young, *supra* note 2 at 22-3.

A secondary concern is that the results of new research may be kept secret for an extended period of time while the researcher perfects the invention to a stage of development that ensures the grant of a patent.[14] One could argue, however, that such secrecy is necessary in order for the inventor to be granted a patent, i.e., it is a requirement under the *Patent Act* that the invention be "new." In addition, there is evidence that university-business joint ventures result in secrecy in university laboratories.[15] Some of these critics are scientists who consider that information regarding the human genome is communal property that should be freely available to other scientists and the public.[16] This concern has been dubbed the "tragedy of the anti-commons" by commentators.[17]

Others point out, however, that patents stimulate invention and promote the disclosure of inventions and thus knowledge, which in turn enables other inventors to learn about them and to develop improvements on the original invention, as well as alternatives. The U.K.'s Nuffield Council on Bioethics[18] described the benefits of patents as follows:

> … [patents represent] one of the most important incentives for commercial enterprises to undertake research and development, by allowing them to enjoy returns on the generation and application of knowledge. The patent system provides an incentive to invest in the production and application of knowledge by allocating benefits directly to those companies making the investments, and because it grants property rights which recognise an inventor's exclusive right to prevent others, for a fixed term, from making, using or selling an invention based on that knowledge without licence. By contrast, the inability or failure of companies to prevent others from making use of the new developments they generate is an established cause of the failure of commercial enterprises… Moreover, because patents facilitate the dissemination of knowledge, they also serve to prevent costly and wasteful duplication of the efforts of researchers.[19]

The Science

In order to fully understand the complex legal and ethical issues raised by patenting human materials, it is important to have a basic understanding of the science involved. This section briefly describes the patenting of human genes, and other human materials, such as cells, as inventions or as part of a patented process.

The term "biotechnology" was coined in 1919 to refer to the science and the methods that permit products to be produced from new materials with the aid of living organisms.[20] Common examples of early biotechnology are the use of living micro-organisms to catalyze chemical reactions to produce certain foods, such as bread and cheese, and the propagation of plants through grafting.[21] Modern or second-generation biotechnology began with Watson and Crick's 1953 discovery of the structure of DNA, the genetic material occurring in living organisms.[22] This discovery heralded a new age of research in which scientists laboured to discover how DNA functioned and how differences in DNA resulted in differences between individuals.[23]

Modern biotechnology is, for the most part, based on molecular biology and operates at the cellular and molecular levels.[24] Scientists are able to exchange genetic information between mircro-organisms, plants, and animals, including humans. In practical terms, genetic modification or engineering has resulted in products that were once only available from natural sources in limited amounts being manufactured in large amounts at low costs. Insulin and human growth hormone are two examples of such products.[25]

---

[14] ALRC, *supra* note 4 at 63.

[15] Ned Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics" (1995) 22 B.C. Envtl. Aff. L. Rev. 267, at 294.

[16] J. Donahue, *Patenting of Human DNA Sequences — Implications for Prenatal Genetic Testing*, 36 Brandeis J. Fam. L., 1997-98, at 274.

[17] E. R. Gold and T. A Caulfield, *supra* note 12, at 30.

[18] Nuffield Council on Bioethics, *supra* note 3.

[19] *Ibid.* at 13.

[20] Tara Snell and Réal Doutre, *Biotechnology: A Reference Guide for Department of Justice Practitioners* (Ottawa: Department of Justice, 2003) at 1 citing B. Sheridan, *EU Biotechnology Law & Practice* (Isle of Wight: Palladian Law Publishing Ltd., 2001) at 3.

[21] P. Reimer and B. Schwartz, "Biotechnology: A Canadian Perspective" (2001) 1 Asper Rev. of Int'l Bus. And Trade Law, para. 2, online: QL (JOUR). Ned Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics" (1995) 22 B.C. Envtl. Aff. L. Rev. 267 at 274.

[22] Nuffield Council on Bioethics, *supra* note 3, at 3.

[23] *Ibid.*

[24] Modern biotechnology began with the Cohen/Boyer Patent. It was the first process/technique for creating a transgenic involving recombinant DNA using plasmids in bacteria. Enzymes were used to insert a synthetic gene into plasmid. The bacteria had in the past had been used to incorporate its DNA into the plant. Now, however, the plasmid transferred the synthetic gene into the plant.

Human Genes

A gene is the functional and physical unit of heredity passed from parent to offspring. Genes are units within the nucleus of a cell that are made up of deoxyribonucleic acid, more commonly known as DNA. Within the cell's nucleus, genes are organized into chromosomes, of which humans inherit a set of 23 from each parent for a total of 46 chromosomes. In interaction with the environment, chromosomes determine a person's physical and to some extent, behavioural characteristics.[26]

The Human Genome Project (the "HGP") begun in 1990 could be considered an indication of the thriving state of genetic research.[27] The intent of the project was to co-ordinate international research to identify and map all the genes in the human DNA, and to order the chemical base pairs that make up human DNA. Research was jointly undertaken by two communities of researchers: those in publicly funded bodies, such as universities and research institutes, and those working in privately funded industrial organizations, such as Celera.[28] The international consortium was led by Dr. Francis Collins of the United States ("U.S.") National Human Genome Research Institute.[29]

In 2001, two versions of the draft map of the human genome were published by the two research communities, with the data from the publicly funded research being incorporated into the results from the privately funded version. The publicly funded research had been conducted in the context of a strong commitment to the public sharing of, and access to, the data.[30] The final sequencing of the human genome was completed in April 2003. The sequence data produced by the HGP was deposited into public gene banks, while Celera and other private organizations, sought patent protection over the sequences they identified.[31]

In 2003, the human genome was estimated to be composed of approximately 30,000 protein-coding genes, and a myriad of other functional elements, such as non-protein-coding genes.[32] More recently, the International Human Genome Sequencing Consortium (made up of several pharmaceutical companies) has announced that the human genome only contains between 20-25,000 protein-coding genes. This is a far cry from the original estimate of 100,000 human protein-coding genes.[33]

The HGP resulted in an enormous increase in the knowledge and understanding of the human genome and it pushed the issue of gene patenting to the forefront of research, medicine and society. The draft of the human genome, released in 2001, allowed researchers to identify genes associated with a number of genetic based disorders and diseases. To date, over 30 genes have been pinpointed and linked to diseases such as breast, skin and colon cancer, muscle disease and Alzheimer's disease.[34]

It is interesting to note that the mapping of the human, mouse and chimp genomes have revealed that 40 to 80 per cent of the human genome is shared with the mouse,[35] while 99 per cent is shared with the chimpanzee.[36] One could argue that the human genome is not just the common heritage of humans but rather significant portions of it are also the heritage of other species. This knowledge may also diminish the notion that the human genome is unique and/or sacrosanct.

---

[25] Tara Snell and Réal Doutre, *supra* note 20, at 2-3, citing William P. Cunnigham et al., eds., *Environmental Encyclopedia*, First ed. (Detroit, U.S.A.: Gale Research Inc., 1994) at 99.

[26] Government of Ontario, "Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare" Draft Report to the Provinces and Territories, (Toronto, 2002) at 13 [hereinafter *Charting New Territory*].

[27] K. Davies, "Cracking the Genome: Inside the Race to Unlock Human DNA" (2001) at 3.

[28] Nuffield Council on Bioethics, *supra* note 3, at 3.

[29] ALRC, *supra* note 14, at 47.

[30] Nuffield Council on Bioethics, *supra* note 3, at 3. The public sector research published the sequence in Nature (Feb. 15, 2001), while the private sector project undertaken by Celera Inc., a United States genomics company, was published in Science (Feb. 16, 2001).

[31] ALRC, *supra* note 14, at 47-8.

[32] Francis s. Collins, et al. (on behalf of the US National Human Genome Research Institute), "A vision for the future of genomics research: a blueprint for the genomic era" (Nature/Vol. 422/24 April 2003) at 3. Online: http://www.nature.com/nature, accessed August 2004.

[33] Nature, 21 October 2004, Online: Human genome: End of the beginning, Nature 431, 915-16.

[34] *Charting New Territory*, *supra* note 26, at 15.

[35] Elizabeth Pennisi, "Sequence Tells Mouse, Human Genome Secrets" *Science Online*, Volume 298, Number 5600 (6 December 2002) p. 1863-65. Online: http//cmbi.bjmu.edu.cn/news/0212/26.htm. Accessed 28 April 2005; NIH/National Human Genome Research Institute, "The mouse genome and the measure of man" (4 December 2002). Online: http//cmbi.bjmu.edu.cn/news/0212/26.htm. Accessed 28 April 2005.

[36] Cornell News, "DNA analysis for chimpanzees and humans reveals striking differences in genes for smell, metabolism and hearing" (18 December 2003). Online: http//www.news.cornell.edu/releases/Dec03/chimp.life.hrs.html. Accessed: 28 April 2005. Newswise, "Lifestyle Accounts for Differences in Chimp, Human Genome" (18 December 2003). Online: http//www.newswise.com/articles/view/502544. Accessed: 28 April 2005.

The raw materials of nature are not patentable since they are discoveries rather than inventions. For the same reason, scientific knowledge about a naturally occurring phenomenon is not eligible for patenting: it is viewed as a mere discovery. Consequently, scientific knowledge about genetic information encoded in some naturally occurring phenomenon is not eligible for patenting and thus the gene and its information inside a human body could not be the subject matter of a patent. However, an artificial phenomenon that does not occur naturally, such as a molecule that has been isolated, identified and cloned, that encodes human genetic information may be patentable.[37]

The distinction between the invention and the discovery of a naturally occurring substance was aptly described by Richard Gold and Timothy A. Caulfield in their paper "Human Genetic Inventions, Patenting and Human Rights."[38] The authors state:

> A DNA sequence, as it exists in a human body, is not an invention. Its occurrence in that body is completely natural and is not due to a technical intervention. That sequence is not, therefore, patentable. *However, this does not mean that the same DNA sequence could not be patented in a different context.* Consider for example, the same DNA sequence extracted from its native cell and placed in a test-tube. *The sequence in that particular form owes its existence to human intervention. It is thus patentable* [as long as it meets the other criterion in the Act]. The patent holder only has, in this case, the right to prevent others from making, using, selling or importing the DNA sequence in this isolated form; *the patent holder has no rights against anyone making use of the DNA sequence in its natural human host.* Nevertheless, should the person with the DNA sequence decide to have a genetic test — which involves removing that DNA sequence from its natural environment and placing it in a test-tube — that person would violate the patent.[39] [emphasis added]

One way to obtain the genetic information contained in a DNA sequence requires the use of cloning techniques. Cell samples are collected and scientists apply enzymes to break the cell apart and to separate the DNA from other chemicals in the cell. Once the DNA is removed, other enzymes are used to break the long DNA molecule into shorter sequences, such as genes, gene fragments, or genetic markers. Chemicals or electrical methods are then used to separate the pieces of DNA into strands of different lengths. These shorter sequences are taken up by vectors and transferred into bacteria which subsequently make copies of these DNA sequences. The cloned DNA is removed from the bacteria and a process known as polymerase chain reaction is used to make thousands of purified copies of the DNA.[40]

Much of the debate surrounding the patentability of human DNA sequences has centered on whether or not they are a discovery of something already existing in nature or whether they can be considered an invention. In patenting terms, the scientific knowledge concerning the genetic information has been discovered through the creation of an artificial molecule. Patent offices around the world have concluded that the genetic information is essentially part of an invention, a molecule which is human handiwork and thus patentable.[41]

This process of isolating and cloning has been the basis for granting patents over DNA sequences in the past. However, the use of computational techniques (relying on computers) to identify DNA sequences of genes is fast replacing the laboratory cloning method described above, and may in the not too distant future call into the question the eligibility for patenting of DNA sequences because of the lack of inventiveness in the computational technique.[42]

---

[37] Nuffield Council on Bioethics, *supra* note 3, at 27.

[38] Gold and Caulfield, *supra* note 12.

[39] *Ibid*, at 22-23.

[40] D. Resnik, "DNA Patents and Human Dignity" (2001) 29 J.L. Med. & Ethics 152 at 154.

[41] Nuffield Council on Bioethics, *supra* note 3, at 27-8.

[42] *Ibid*, at 28. The *in silico* approach or technique to identifying DNA sequences is unlikely to provide the grounds for eligibility for patenting in Europe as it does not involve any laboratory work. It relies on the fact that the human DNA sequence is now available from a personal computer. The researcher simply matches an unknown human DNA sequence to a homologous, or similar, gene sequence in an animal genome where the function may already be known. The researcher then files a patent application on the human DNA sequence, in the context of a diagnostic or therapeutic use, based on the similarity of function. Although this process may not meet the test used by the European Patent Office, it will likely meet the lower threshold of inventiveness used by the United States Patent and Trademark Office.

In order to receive a patent on an invention, it must be new, non-obvious and useful. Patents on isolated gene sequences and their associated proteins have been granted since the 1980s on the basis that the protein might be a useful therapeutic at some point.[43] The patent granted the "inventor" a monopoly over the "isolated sequences, the purified protein, various vectors used to transform production organisms with the relevant sequence, and the transgenic organisms used to produce large quantities of the protein."[44] Patent law theory allowed these materials to qualify as inventions since none had previously existed in nature in their isolated or purified form (additionally, the transgenic production organisms were novel). The scope of such a patent is broad enough to allow a pharmaceutical company to bring to market (after clinical trials and research) a drug or other product based on the therapeutic protein. [45]

The scope of what is patentable continues to expand in many jurisdictions, especially the U.S. For example, patents have now been granted on partial gene sequences that might be useful in identifying a gene, and on genes that are no longer identified through protein production but through computer analysis. In 2001, the U.S. Patent and Trademark Office ("PTO") issued Utility Examination Guidelines[46] which provided standards regarding the amount of knowledge one must have about the biological significance of a sequence before it can be patented.[47] However, this has not stopped patenting from expanding further still. The U.S. now issues patents on protein co-ordinates. These patents are monopolies over the use of the measured co-ordinates in computer programs to attempt to model the interaction of the protein with other chemicals that might be candidates for therapeutics. In addition, patents have been issued in the U.S. on diagnostic sequences, including single nucleotide polymorphisms ("SNPs")[48] and expressed sequence tags ("ESTS").

Scientists working on the HGP produced and published a map of 1.42 million SNPs. SNPs are sites in the genome at which single nucleotide bases differ from person to person and appear to occur at a frequency of approximately 1 per 1900 bases.[49] Variations in DNA sequence can have a major impact on how humans respond to disease, environmental insults, such as bacteria, viruses, toxins and chemicals, as well as drugs and other therapies. SNPs are thus quite useful tools in biomedical research.[50] SNPs have value as markers for linkage or for association studies of genetic susceptibility to disease.[51] To date, SNPs maps have identified DNA sequences underlying such common diseases as cardiovascular disease, diabetes, arthritis, and some types of cancer. The hope is that the identification of disease genes and SNPs will allow scientists to target the development of new drugs and therapies.[52]

ESTs are parts or fragments of a gene.[53] Often these are patented without a description of the exact location of the original gene on the chromosome and without a description of its biological function. The patenting of these fragments has become controversial among scientists and many have argued that both SNPs and ESTs are biological research tools that should not be patentable.[54] It appears that the U.S. PTO may have recently adopted a more restrictive approach to the issuing of these patents.

Many of these patents present significant problems to the U.S. pharmaceutical industry because the materials patented are research tools useful for the development of therapeutics and new drugs. Biotechnology companies have acquired patents to many of these with the intent of supplying them under contract (licence) to pharmaceutical companies.[55] One could argue that one of the social benefits of patenting, i.e., the distribution of inventions, as well as the disclosure of knowledge and information within society, is being lost through the expansion of patentability.

Thousands of patents with claims to human DNA sequences have been filed and granted, mostly in the U.S. These include patents for genomic DNA sequences, SNPs, DNA sequences of individual mutations that give rise to disease, cloning vectors, proteins and parts of proteins, and computer-assisted methods for identifying proteins or parts of proteins of similar structure. Currently, there are over 3 million genome-related patent applications filed with the U.S. PTO.[56]

---

[43] John H. Barton, "Genomics Patents" at 101, in Bartha Maria Knoppers and Charles Scriver, eds., *Genomics, Health and Society: Emerging Issues for Public Policy* (Ottawa: Policy Research Initiative).

[44] *Ibid.*

[45] *Ibid.*

[46] 66 Fed. Reg. 1093 (5 January 2001).

[47] Barton, *supra* note 43 at 102.

[48] *Ibid.*

[49] WHO Genomics and World Health at 2.4.3 page 32.

[50] *Charting New Territory, supra* note 26, at 38.

[51] WHO, *supra* note 49, at 32.

[52] *Charting New Territory, supra* note 26, at 15.

[53] *Ibid.* at 37.

[54] *Ibid.* at 37-8.

[55] Barton, *supra* note 43, at 103.

Other human materials

Technology has produced new ways of using human bodily materials in research. Human materials are not only used in biomedical research but also as a component of a variety of commercial products ranging from drugs to vaccines to pregnancy test kits.[57] Many of the results of such research, especially where it has a commercial or research application, will become the subject matter of a patent.

The most common technologies employed to convert human materials, tissues and cells, into products are: cell culture technology, hybridoma technology and recombinant DNA technology.[58] Cell culture technology involves the use of human cells that continually divide and grow in culture. Most, but not all, of the established cell lines originated from malignant tissue samples.[59] Successful cell lines begin with the isolation and expansion of a single cell a process referred to as cloning.[60] The resulting cell cultures are used in many types of commercial and non-commercial research. They can be used as a biological factory to produce a substance and to test drugs or the toxicity of various chemical compounds.[61] These cell cultures are often the subject matter of a patent.

Hybridoma technology uses hybridomas which are special types of hybrid cells created by the fusion of two different types of cells, a type of tumour cell called a myeloma and a B lymphocyte cell.[62] The B lymphocyte cell is isolated from the spleen or lymph node tissue (part of the body's immune system), which has been injected with the specific foreign substance of interest to the researcher. The B lymphocyte is a specialized type of white blood cell that produces one specific kind of antibody in response to the injection. When the B lymphocyte is fused with the immortal myeloma cell, the resulting hybridoma continuously multiplies in culture and secretes a single specific type of antibody. The supply of large amounts of specific antibodies is important for research, medicine and commerce. They can be used in diagnostics and for prophylactic or therapeutic regimens in humans. [63]

The third type of technology is referred to as DNA recombinant technology (also referred to as genetic engineering). Donor DNA is cut by enzymes into fragments, one of which contains the sequence of interest. These fragments are joined with vector DNA (vectors can be bacterial, viral, phage or eukaryotic DNA or combinations of these DNA) to become recombinant DNA molecules. The recombinant molecules are then introduced into host cells. The host population containing the cloned gene can be expanded and the cloned gene used to identity, isolate and scrutinize scarce biological compounds.[64]

There are three major sources of human tissues and cells for research: patients, healthy volunteers and cadavers. Specimens obtained from patients can be both normal and atypical, but most are obtained as "leftovers" from diagnostic or therapeutic procedures.[65]

Human reproductive materials, including sperm, ova, and *in vitro* embryos are also the subject matter of research, and some of these materials have been considered patentable. Embryonic Stem cells derived from human *in vitro* embryos are viewed as potentially valuable research materials and have been the subject of patents in the U.S. and elsewhere.[66]

---

[56] Johnathan Kahn, "What's the Use? Law and Authority in Patenting Human Genetic Material" (2003) 14 Stan. L. & Pol'y Rev. 417 at 421-2.

[57] Office of Technology Assessment, *New Developments in Biotechnology Ownership of Human Tissues and Cells — Special Report*, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, 1987) at 23.

[58] *Ibid.* at 31.

[59] *Ibid.* at 33.

[60] *Ibid.* at 34.

[61] *Ibid.* at 35.

[62] *Ibid.* at 35-8.

[63] *Ibid.* at 38; Maureen s. Dorney, "Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation against the right of Informed Consent" at 3.Online: http://www.law.berkley.edu/journals. Accessed August 2004.

[64] *Supra* note 57, at 43-4.

[65] *Ibid.* at51.

[66] In April 2003, the UK PO issued a practice note setting out its position re the patentability of cells from the human embryo. The UK PO will not grant patents for processes for obtaining stem cells from human embryos since it views such processes as excluded from patentability by virtue of the EPC *Directive*. In addition, it will not grant patents over human totipotent cells since they have the potential of developing into an entire human being. However, the PO will issue patents over human embryonic pluripotent stem cells derived from further division of the totipotent cells and which do not have the potential for developing into an entire human body. The PO considers that there embryonic pluripotent stem cells fall neither within articles 5(1), 6(1) or 6(2)(c) of the *Directive* (Boult Wade Tennant bulletin (European Patent and Trade Mark Attorneys, Patenting Stem Cells in Europe, August 2004) http://www.boult.com/information/BulletinPrint.cfm. Accessed March 14, 2004).

6.3 Property Rights in the Human Body

At first glance, it may appear that there is no connection between the subject of property rights in the body and the question of patenting and human rights. One can argue, however, that on closer examination the principle of human dignity may be the connector. This possible connection is further explored in the following discussion.

Patents over human materials essentially grant to the inventor intellectual property rights in the invention and in any extracted human materials which form part of the invention. Concerns have been expressed by human contributors of biological materials that they rarely receive a benefit from such contributions nor are they permitted to benefit by selling their biological materials in the marketplace. If inventors are able to commercialize products based on or containing donated human materials, and possibly realize substantial profits, why can an individual donor not commercialize and realize a profit from the sale of his or her excised materials, or benefit from his or her donation? The answers may lie in the commonly held Western view of the body as being inseparable from the soul and personhood.

Early philosophical writings by Plato and others on the significance of the physical body considered it an impediment: it was seen as a temporary tomb in which the soul was forced to reside.[67] This view of a split between the soul and the body was widened by the writings of more recent philosophers, such as Rene Descartes.[68] In the field of bioethics, philosopher H. Tristram Engelhardt espouses that personhood goes with consciousness, with the brain and not the body.[69] Engelhardt considers the human body to be the quintessential example of property and believes that human beings have a right to trade commercially in the body. Persons should be free to consent to do what they wish with their body.[70]

Other early philosophers, such as Aristotle, considered the body and soul as two aspects of a single entity.[71] This view is reflected in the Jewish and Christian traditions. Both traditions embraced the notion that the fleshly body is entwined with the soul.[72] Paul Ramsey, a Christian theologian, captured this view with the following statement "Persons are either embodied souls or ensouled bodies."[73] In his view, the body is a "sacredness" in the biological order and thus commercialization of the body would be seen as "morally repugnant."[74]

In Western culture, the most prevalent view of the human body is that found in the Jewish and Christian religious traditions. According to this view, the body is bound up with the soul: the body houses the soul and thus the very essence of the person. The secular notion that the human body and human dignity are linked makes commercialization of the body or its products repugnant to many North Americans and Europeans.

One might argue, however, that this viewpoint has not always been reflected in the common law, since there are situations where the law recognizes a limited property right in the human body. On the other hand, one could argue that it is precisely because the body is considered as an object of rich moral significance that the law and society consider it as "property," solely to ensure that certain legal remedies are available for offences committed against it.[75]

In order for property to be recognized in an object, not all the elements or rights that make up property have to be present.[76] The common law, for example, grants to immediate family members a limited property right, in the nature of control, in the body of a deceased relative.[77] This right does not permit the family members to sell the body or its parts, rather it provides them with the necessary control to dispose of the body according to the wishes of the deceased. It also provides the family members with the right to claim compensation for emotional distress in those situations where the corpse has been mistreated.[78] Additional examples abound where the common law recognizes limited property rights in the body. The tort of appropriation of name or likeness and the tort of battery are examples of common law remedies that recognize limited property rights in the body. Canada's *Criminal Code* includes the offences of battery and assault, indicating the importance society and Parliament place on an individual's control over the integrity of their body.

---

[67] Thomas H. Murray, "On the Human Body as Property: the Meaning of Embodiment, Markets and the Meaning of Strangers" (1987) 20 U. Mich. J.L. 1055 at 1063.

[68] *Ibid* at 1064.

[69] *Ibid* at 1067.

[70] *Ibid* at 1068-69.

[71] *Ibid* at 1069.

[72] *Ibid* at 1069-70.

[73] *Ibid* at 1070.

[74] *Ibid* at 1071.

[75] *Ibid* at 1063.

[76] Honore identified eleven elements or rights that constitute property. They include the right to: possess, use, manage, draw an income from, transmit or destroy, enjoy protection from expropriation, dispose of the interest on death, hold the property forever, residual or reversionary interests, and two other features: liability to seizure for debts and prohibition on harmful use. (A.M. Honore, "Ownership," in *Oxford Essays in Jurisprudence*, A.G. guest ed. (1961) at 107. Bruce Ziff, *Principles of Property Law* (Scarborough: Carswell Thomson Publishing, 1993) at 2.)

[77] *Lubin v. Sydenham Hosp.*, 181 Misc. 870, 42 N.Y.S.2d 654 (N.Y. Sup. Ct. 1943).

The common law has also recognized ownership rights over the body's reproductive materials, such as sperm and *in vitro* embryos.[79] In addition, there are limited property rights granted in legislation. For example, every Canadian province has a statute that allows individuals to make a gift of parts of their body during their lifetime (*inter vivos*) and after death (*causa mortis*).

In the pivotal American case of *Moore v. The Regents of the University of Southern California et al*,[80] the courts were asked whether an individual who had unknowingly contributed parts of his body to researchers who subsequently used them to create a profitable patented cell-line, named the Mo cell-line, could successfully sue the researchers for the tort of conversion.[81] A majority of the California Court of Appeal found that Mr. Moore could sustain a cause of action for conversion, since in its view individuals had the "essence of a property interest – the ultimate right of control" with regards to their own body.[82]

On appeal, the California Supreme Court was split five members to two. The majority held that Mr. Moore did not have a cause of action for conversion, since he had no ownership interest in his excised cells.[83] He did, however, have the basis for an action in negligence against the physician since he had not obtained Mr. Moore's informed consent to the removal and donation of his excised cells and tissues for research purposes.[84]

One of the two dissenting opinions, written by Justice Mosk, noted that under the laws of California, property is a broad concept. In his view, Mr. Moore was seeking fairness and equity to some share in the profits that defendants made and expected to make from his cells. He wrote "... no one can question Moore's crucial contribution to the invention – an invention named, ironically, after him: but for the cells of Moore's body taken by defendants, there would have been no Mo cell line."[85]

The irony evident in the *Moore* decision is that while researchers and the biotechnology industry are at liberty to make potentially large profits by mining, refining and patenting human materials, the source or individual donor of the raw materials is not able to sell their bodily materials in the marketplace and is not required by law to receive a benefit back from the patentee.

6.3.1 The Principle of Human Dignity

Many writers have expressed concern that the recognition of property rights in the body would negatively impact human dignity. The worth of individuals would be seen in terms of their commercial value in the marketplace rather than in terms of their inherent worth, which is "neither given by the state nor vulnerable to political whim, totalitarian or majoritarian, either within or beyond national borders."[86]

Human dignity, while not a free-standing constitutional right, can be described as a fundamental principle[87] or a constitutional value that underlies many of the rights in the *Canadian Charter of Rights and Freedoms*[88, 89] The concept of dignity is likely implicated in any issue involving human rights since it is considered intrinsic to every human being, and is one of the values and principles essential to a free and democratic society.[90]

---

[78] *Supra* note 67, at 1062-63.

[79] *Hecht v Superior Court*, 16 Cal. App. 4th 836; 20 Cal. Rptr. 2d 275, 1993 Cal. App. LEXIS 638, 93 Cal. Daily Op. Service 4531; 94 Daily Journal DAR 7656, No. B073747 (Court of Appeal of California); *Davis v Davis* (1992), 842 S.W.2d 588 (Supreme Court of Tennessee).

[80] *Moore v. The Regents of the University of California et al.*, No. B021195 (QL) (Court of Appeal of California) July 21, 1988 [hereinafter referred to as *Moore CA*]; *Moore v. the Regents of the University of California et al.*, No. S006987 (QL) (Supreme Court of California) July 9, 1990 [hereinafter referred to as *Moore SC*].

[81] The tort of conversion is an action for the wrongful conversion of something to one's own use (Shorter Oxford English Dictionary, 3rd Edition).

[82] *Moore CA*, *supra* note 80 at 8.

[83] *Moore SC*, *supra* note 80 at 14.

[84] *Ibid.* at 5.

[85] *Ibid.* at 29.

[86] Lorraine E. Weinrib, "Human Dignity as a Rights-Protecting Principle" (Ontario Bar Association, CLE, 3rd Annual Charter Conference, October 2004) at 3.

[87] *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307, at para. 97.

The notion of human dignity can be considered from two different viewpoints, i.e., objective and subjective. Objective dignity is said to encompass "unconditional and incomparable worth… [an] unchanging, supreme value that inheres in every human being."[91] Dignity is a constant and is not dependent on the person's circumstances or the respect shown to him or her by others in society.

Subjective dignity, on the other hand, is a personalized, individual sense of self-worth. This sense of dignity is not concerned with an abstract ideal of equal concern and respect, but with "the individual's own perception of self-worth."[92] It is dependent on whether the individual has a sense of self-worth as a human being or whether they feel worthless: it is a conception of self-respect.[93] It is specific to the particular individual. When the Supreme Court of Canada undertakes an analysis that includes human dignity, for example, when deciding a question of discrimination, it considers the impact of a government action on both subjective and objective dignity.

Would an individual's feelings of self-respect or self-worth be diminished if the state granted property rights in the body or bodily materials? Is the body sacred, housing an individual's essence or personhood, or is it nothing more than an impediment? Would a right to commercialize the body affect an individual's physical or psychological integrity of empowerment? Does the grant of a patent over excised bodily materials offend human dignity?

For many individuals, the existence of a legal market for body cells or parts would diminish human dignity. The body and the person are so intimately connected that affronts to the physical body would be affronts to the person. The notion that an individual could be reduced to and viewed as a conglomeration of marketable parts and materials would impact on their subjective feelings of self-worth and self-respect, and on their objective view of human beings as possessing incomparable and priceless worth.

For others, the fact that human materials are taken and used to produce patentable products sometimes resulting in significant profits for inventors and biotechnology companies would also diminish the concept of human dignity. The government grant of patent rights assigning to the patentee intellectual property rights over the product would be troubling.

There are still others, who view the body as separate and distinct from personhood and who would find nothing wrong with property rights in the body. Property rights in the body would not diminish human dignity, which is accorded to the person who inhabits the body, but not the body itself. For these persons, the body is morally insignificant and lacking in any intrinsic dignity. In fact, these individuals may consider it offensive that one segment of society can profit by using bodily materials in an invention, while the donor of the raw materials has no right to a share in that profit.

6.3.2 Discussion

The common law has evolved to recognize individual quasi-property rights in the body. Despite, however, the opportunity presented by *Moore, supra*, the common law has declined to evolve further and grant rights to alienate the body for valuable consideration, such as money, or to be compensated for bodily materials taken without consent.

Researchers and corporations routinely claim intellectual property rights over human materials that they have invented. If the Patent Commissioner determines that the invention meets the requirements for a patent, he or she must issue a patent granting the patentee the right to exclude others from using, making or selling the invention. The right to exclude others from using an object is considered by some to be the essential right that an individual must possess in order to categorize an object as

---

[88] *Canadian Charter of Rights and Freedoms*, enacted as schedule B to the *Canada Act 1982*, (U.K.) 1982, c. 11 [hereinafter referred to as the *Charter*]

[89] Dierk Ullrich, "Concurring Visions: Human Dignity in the Canadian Charter of Rights and Freedoms and the Basic Law of the Republic of Germany" (2003) 3.1 Global Jurist Frontiers 1 at 25.

[90] *R. v. Oakes*, [1986] 1 S.C.R. 106 at 163.

[91] Sophia Moreau, "The Wrongs of Unequal Treatment" (2004) 54 U of T L.J. 291 at 295.

[92] *Ibid.* at 313.

[93] *Ibid.*

property. Clearly, these biological materials/inventions are property.

Although a patent represents intangible property, one could argue that because it grants the patentee exclusive use of the invention, for example, an isolated DNA sequence in the field of biotechnology, it provides the patentee with aspects of a tangible property right in the subject matter of the patent. This is especially the case where the "invention" differs very little from the raw materials. Concerns have been expressed by authors and in government reports that with respect to human genes, the scope of patentable subject matter is constantly being expanded and in many cases, critics have argued that the usefulness or biological function of the invention is unknown at the time of patenting.[94] Others, however, have pointed out that "usefulness" remains a necessary criterion in order to receive a patent.

In the U.S., patents are issued for protein co-ordinates, SNPs, such as the BRCA diagnostic sequence (for breast cancer), and ESTs. These patented biological materials may be more appropriately characterized as research tools. Protein co-ordinates may have little or no independent value and yet can be the subject of a patent. Their real economic value derives from a final product, e.g. a pharmaceutical that is developed with the aid of the research tool.[95]

The expanding scope of patentability in the U.S. suggests a contradiction in the law. The law refuses to grant individuals property rights in their bodily materials and yet allows pharmaceutical and biotechnology companies intellectual property rights over these materials, despite the fact that some of the patented materials require very little in the way of inventivenss or differ very little from the naturally occurring material in the body. In the past, the granting of property rights in bodily materials could be explained by applying John Locke's theory of property. The inventor, using raw materials, such as human cells, applies his physical and mental labour to produce or create a product. The inventor, as a human being, has an inalienable right to self-ownership and it is this right combined with the inventor's physical and mental labour that gives him or her a right of property in the finished product. The theory is that the finished product is different from the raw materials, i.e., the excised human materials. The inventor has no property rights over the human materials in the donor's body. The state's grant of intellectual property rights, in the form of a patent, is only with respect to the finished product and not the bodily materials occurring in the human body.

John Locke's theory of property may no longer fully explain intellectual property rights over all biological inventions. For example, the use of computational techniques to identify DNA sequences requires minimal physical or mental labour to produce a patentable invention. As noted earlier, some American critics suggest that the criterion of usefulness necessary to obtain a patent is no longer as strictly applied resulting in patents being granted for inventions despite the fact that its use is not always clear when the patent is issued. If these criticisms prove valid, the rationale for allowing inventors to acquire property rights over excised human materials may be questionable. Moreover, if inventors can attain property rights in human materials with little to no labour, the strength of the argument that individuals cannot be assigned property rights in their own excised bodily materials because they have not contributed physical or mental labour would be diminished.

The continued successful commercialization of inventions composed of human materials by the biotechnology industry, with no benefit back to the respective donors, may itself come to be regarded as an affront to human dignity. Donors may increasingly feel exploited as sources of raw materials and may experience feelings of diminished self-respect and self-worth. Litman and Robertson raised similar concerns with respect to human dignity.[96] They hypothesized that by disallowing individuals exclusive control of their bodies and any excised materials, respect and human dignity would both be diminished.[97] This may be in part what the Court of Appeal in *Moore, supra,* was concerned with when it observed that the right to one's own genetic materials and the power to control excised bodily tissues protects both human privacy and dignity.[98]

---

[94] Barton, *supra* note 43 at 102; *Charting New Territory*, supra note 26, at 37.
[95] Barton, *ibid* at 102-03.
[96] Moe Litman and Gerald Robertson, "The Common Law Status of Genetic Materials," in Bartha Maria Knoppers, Timothy Caulfield and T. Douglas Kinsella, eds., *Legal Rights and Human Genetic Materials* (Toronto: Edmond Montgomery Publications Ltd., 1996).
[97] *Ibid.* at 60.

6.3.3 Conclusion

Although there is no human right to property in the body, the fact that quasi-property rights are granted in the body to preserve its moral significance may indicate that the door to this possibility has not been closed. Notions of moral significance of the person and human dignity are closely connected. The fact that corporations can mine, refine and patent parts of the human body in order to reap possible profits, coupled with the fact that the donor has no legal mechanism to force the recognition of his or her contribution, may be considered by many as an affront to their human dignity. Individual donors may be left feeling exploited; their only significance being as a source of raw materials.

There is no legal obligation on the patentee to recognize the contributor of materials, either through a share in the profits or a benefit back to the community. The balance is clearly weighted in favour of industry. Property rights in the human body or a human right to property in the body may be one way of righting the balance.

Others may dismiss this position by arguing that the community does receive a benefit back in the form of inventions and in the case of biomedical research, in the form of possible cures for disease. For persons and communities who have sacrificed their time and resources to donate bodily materials and raise money for biomedical research that results in very profitable inventions, more recognition may be justified.

An argument could be made that in order to preserve human dignity, the law may have to evolve to ensure that donors of human bodily materials receive a "benefit back" in those instances where the product proves to be of commercial value. This solution, while not granting persons unlimited property rights in the human body, would ensure that inventors and donors are treated equally. Both would be recognized by society for their valuable contribution to increased knowledge and to inventiveness that has the potential to provide cures to many debilitating human diseases.

Unjust enrichment and the tort of conversion may provide the most compelling legal basis on which the donor may to stake a claim to a share of the patentee's profits. To succeed at either, the courts would have to recognize limited property rights in the human body and its excised cells and tissues. A strong argument could be made that recognition by the common law of property rights in the human body would not be precedent setting. Individuals already possess a number of the elements indicative of such a property right, for example, the right to control, which is arguably the strongest indicator of property rights in an object.

6.4 Patents and Human Rights

To date, there have been no allegations that patenting infringes human rights. Some academics have made statements to that effect, but a thorough analysis of the assertion has been lacking. In an attempt to rectify the situation, this section of the chapter provides three hypothetical scenarios to assist in an analysis to determine whether the patenting raises and engages human rights.

The discussion begins by setting out: (1) international law and principles, (2) the law in other jurisdictions, (3) Canadian law, and (4) academic commentary.

6.4.1 International and Regional Instruments

International Trade Agreements

TRIPS

Canada is a member of the WTO and thus must comply with the provisions of the 1995 WTO agreement on the *Trade-Related Aspects of Intellectual Property Rights*[99] ("TRIPS"). Member States must comply with the articles in TRIPS, which set out the rules regarding different types of intellectual property, including copyright, trademarks, industrial designs, and patents.

---

[98] *Moore CA, supra* note 80.

[99] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Legal Insturments-Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994) [hereinafter referred to as "TRIPS"].

Article 27, paragraph (1), of TRIPS provides that patents are available for an invention that meets the basic criterion of newness, inventiveness and industrial application. Members may not discriminate with respect to the grant of patents over technology, unless it is in accordance with one of the possible exemptions. TRIPS provides Members with the ability to exclude from patentability inventions that may violate *ordre public* or morality, as follows:

> 27.2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The TRIPS Council is authorized to monitor compliance with the obligations of each Member State and it provides procedures for dispute settlement. When TRIPS took effect, developed countries, including Canada, were given one year to ensure that their laws and practices were compliant. The WTO regularly reviews Members' trade policies to ensure compliance with all trade agreements. In the event of a dispute between Members with respect to compliance, the Dispute Settlement Body would establish a panel to consider the case and if the offending Member refused to comply with a ruling, it has the power to authorize retaliation, including trade sanctions.

NAFTA

Canada signed the *North American Free Trade Agreement* (the "NAFTA") in 1994, along with the U.S. and Mexico. For the purposes of NAFTA, the three nations become a free trade zone for the conduct of business, including IP. Article 1709:2 of the NAFTA provides any one of the three Member States the option of excluding an object from patentability on the basis of *ordre public* or morality.

International Human Rights Instruments

The United Nations (U.N.) human rights instruments do not directly address questions of patenting. The instruments instead provide general principles that can be referred to for guidance.

Article 12 of the *International Covenant on Economic, Social, and Cultural Rights*[100] recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and sets out the steps to be taken by States to allow individuals to realize the right. Article 12 states:

> 12.1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> a. The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>
> b. The improvement of all aspects of environmental and industrial hygiene;
>
> c. The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> d. The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The United Nations' Committee on Economic, Social and Cultural Rights provided guidance as to the interpretation of article 12 in its General Comment No. 14.[101] The General Comment noted that "[h]ealth is a fundamental right indispensable for the exercise of other human rights."[102] In article 7 of the General Comment, the Committee noted that the right to health is not to be understood as a right to be healthy, but rather it is composed of freedoms and entitlements. The Committee cautioned that the right to health does not impose upon States Parties an obligation to ensure that every citizen experiences good health and is never sick. Many of the factors influencing a person's health are beyond the State's control, such as genetic factors and lifestyle choices. Rather, the right to health should be understood as a right to enjoy a "variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."[103]

---

[100] *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976) [hereinafter referred to as "the ICESCR"]. The *Universal Declaration of Human Rights* provides in article 27 (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits and in article 27(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

[101] General Comment No. 14 (2000), Distr: GENERAL E/C. 12/2000/4, 11 August 2000.

[102] *Ibid.* at article 1.

Article 15.1 of the ICESCR provides:

> 15. 1. The States Parties to the present Covenant recognize the right of everyone:
>
> - To take part in cultural life;
> - To enjoy the benefits of scientific progress and its applications;
> - To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

As noted in both chapters 2 and 3, there is not an abundance of literature and commentary with respect to either the rights of individuals or the State's obligations under article 15.1. In 2001, the Committee on Economic, Social and Cultural Rights, as a follow-up to its day of general discussion, adopted a statement on intellectual property and human rights.[104] The objective of the statement was to "... identify some of the key human rights principles derived from the ICESCR that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes."[105]

In the statement, the Committee was careful to distinguish between human rights and legal rights in intellectual property regimes. It stated:

> The fact that the human person is the central subject and primary beneficiary of human rights distinguishes human rights, including the right of authors to the moral and material interests in their works, from legal rights recognized in intellectual property systems. Human rights are fundamental as they derive from the human person as such, whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits. In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for under article 15 of the Covenant does not necessarily coincide with what is termed intellectual property rights under national legislation or international agreements.[106]

The statement provides grounds for making a distinction between fundamental human rights and an author's or inventor's intellectual property rights, and for assigning more significance and weight to those rights that arise from the human person. With respect to the purpose of intellectual property regimes, the Committee stated that "... intellectual property is a social product and has a social function" which should "serve the objective of human well-being."[107]

---

[103] *Ibid.* at articles 8 and 9.

[104] U.N. Press Release, Committee on Economic, Social and Cultural Rights Adopts Statement on Intellectual Property and Human Rights, 27th Session, 26 November 2001.

[105] *Ibid.* at para. 2.

[106] *Ibid.* at para. 6.

[107] *Ibid.* at para. 4.

The Committee identified a number of human rights principles that deserve attention when adopting intellectual property regimes. For instance, the Committee stressed that equality rights must be protected and particular attention must be paid to disadvantaged individuals and groups.[108] The Committee also stressed the importance of participation in decision-making by those who would be affected by intellectual property regimes.

With respect to States Parties' ability to fulfil their obligations relating to rights enunciated in the ICESCR, the Committee stated:

> The Committee wishes to emphasize that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.[109]

In relation to international cooperation and assistance, the Committee stressed that "[i]t is essential that intellectual property regimes facilitate and promote development cooperation, technology transfer and scientific and cultural collaboration."[110] The Committee suggested that intellectual property regimes need not be identical and encouraged the formulation of special and differential treatment for developing countries.[111]

The Committee prepared a draft General Comment on article 15.1(c) which it shared with experts in August 2004 and considered during its 33rd session in November 2004. The Committee did not adopt the draft during the recent session since it is still under review.

At least one academic, Dr. Audrey Chapman, has written extensively about article 15. She noted that the ICESCR is the major international human rights instrument that addresses the issue of balancing the rights of inventors and creators with the broader interests of society.[112] However, for a number of reasons, these rights and corresponding duties have not been well developed. She speculated that economic globalization and increasing privatization and commercialization of science have made it difficult to achieve the balances required by article 15.[113] Despite the fact that more than 130 countries are signatories to the ICESCR and thus are legally obligated to comply with the provisions, Chapman noted that policy makers and legislators for the most part fail to include human rights considerations in their "decision-making on intellectual property regimes, and instead rely primarily on economic considerations."[114] She referred to the work of C.G. Weeramantry, who wrote in the early 1980s about the implications of unfettered technological advance. In his view, the speed of technological change in society has resulted in a situation where today technology leads, rather than is shaped by, governmental policy. Furthermore, shifts in power have occurred, particularly the concentration of power in transnational corporations and the ability of these corporations to find a common interest with personnel in government departments at the expense of the democratic process. This results in major decisions regarding the use of technology often being made at the highest legislative and executive levels, to which public interest groups have little access.[115]

Dr. Chapman suggested that the balancing required under article 15 imposes a higher standard for evaluating patent applications, namely an approach that considers whether the proposed invention is consistent with the inherent dignity of the human person and with central human rights norms.[116]

But, what are the human rights norms or principles that should be considered by the State under article 15? Chapman suggested that article 15.1(b), contains three human rights components: (1) a right of access to beneficial scientific and technological developments, (2) a right of choice in determining priorities and making decisions about major scientific and technological developments, and (3) a right to be protected from possible harmful effects of scientific and technological development on both individual and collective levels.[117] For example, a right of access to beneficial scientific and technological developments implies at a minimum the freedom and opportunity to benefit from scientific advancement "without discrimination on the basis of race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status."[118]

---

[108] *Ibid.* at para. 8.

[109] *Ibid.* at para. 12.

[110] *Ibid.* at para. 15.

[111] *Ibid.*

[112] A.R. Chapman, "A Human Rights Perspective on Intellectual Property, Scientific Progress, And Access to the Benefits of Science" (1998) at 1. Online: http://www.wipo.org (accessed on 18 June 2004).

[113] *Ibid.* at 3.

[114] *Ibid.* at 2.

[115] C.G. Weeramantry, *The Slumbering Sentinels: Law and human rights in the wake of technology* (Ringwood, Victoria, Australia and Harmondsworth, Middlesex, England: Penguin Books, 1983) chapter 10.

[116] Chapman, *supra* note 112 at 2.

Article 15.1(c), imposes on States Parties an obligation to protect the moral and material interests of authors and inventors. Dr. Chapman noted, however, that it grants States Parties broad discretion in establishing a system for conferring intellectual property protection.[119] This discretion could be used to design patent systems or regimes which do take into account human rights. She suggested that the right to intellectual property as a universal human right is different from the economic interests that result from traditional intellectual property law.[120] In order to respect human rights norms, the subject-matter of the intellectual property rights and the system of patent protection must be consistent with the following principles:

1. Intellectual property rights must be consistent with the understanding of human dignity in the various international human rights instruments and the human rights norms defined therein;
2. Intellectual property rights related to science must promote scientific progress and access to its benefits;
3. Intellectual property regimes must respect the freedom indispensable for scientific research and creative activity; and
4. Intellectual property regimes must encourage the development of international contacts and cooperation in the scientific and cultural fields.[121]

In Dr. Chapman's view, a human rights approach imposes requirements on the State to undertake "a very rigorous and desegregated analysis of the likely impact of specific innovations, as well as an evaluation of proposed changes in intellectual property paradigms... it calls for particular sensitivity to the effect on those groups whose welfare tends to be absent from the calculus of decision-making about intellectual property..."[122]

It is her opinion that, from a human rights perspective, intellectual property should be viewed as a social product with a social function.[123] The *ordre public* or morality clauses contained in the *European Patent Convention* and the *Directive 98/44/EC* on Biotechnology are one means of ensuring that intellectual property rights are consistent with international human rights norms.[124]

> The Preamble to the 1997 UNESCO *Declaration on the Human Genome and Human Rights* emphasizes that research on the human genome "should fully respect human dignity, freedom and human rights."[125] Article 2 states:
>
> a. Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
>
> b. That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.[126]

Article 4 provides that the human genome in its natural state should not give rise to financial gain. The *Declaration* has not, however, had much effect in practice with respect to what can and cannot be patented in most developed countries.[127]

---

[117] *Ibid.* at 2 and 9.

[118] *Ibid* at 9.

[119] *Ibid.* at 13.

[120] A.R. Chapman, "The Human Rights Implications of Intellectual Property Protection" (2002) JIEL 861.

[121] *Supra* note 112 at 13.

[122] *Ibid.* at 10.

[123] *Supra* note 120 at 4.

[124] *Supra* note 112 at 13.

[125] *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, 29th Sess., (adopted unanimously and by acclamation). Under international law, a Declaration is not binding on state parties but rather a sign of support for the principles contained therein. For more information see chapter 1 *supra*.

[126] *Ibid* at article 2.

[127] S. Thambisetty, "Study Paper 10: Human Genome Patents and Developing Countries" Background Paper, Commission on Intellectual Property Rights at 13. [hereinafter *Study Paper 10*]

Article 8, paragraph (j), of the U.N. *Convention on Biological Diversity* ("CBD") provides that State Parties must encourage the equitable sharing of benefits arising from the use of indigenous and local knowledge tied to biological diversity.[128] The Human Genome Organization's ("HUGO") Ethics Committee has stated that the concept of benefit sharing developed under the CBD should be extended to human genetics research, such that commercial entities devote a percent of their net profits to healthcare infrastructure or humanitarian efforts.[129] The rationale for "benefits back" being the commonality of the human genome and as well, reasons of compensatory, procedural and distributive justice.[130]

Regional Instruments

THE EUROPEAN UNION

In 1997, the Committee of Ministers of the Council of Europe concluded the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*.[131] It is legally binding on those State Parties that are signatories. The *Convention* provides that States "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."[132]

The *Convention* was intended to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. It declares that the interests of human beings must come before the interests of science or society.[133] Canada is not a party to the *Convention*; however it does have observer status. Although the *Convention* could not form the basis of a complaint in a Canadian court, it could be introduced to inform the courts of how an intergovernmental organization in Europe has dealt with these issues.

The objective of the *Convention* is found in article 1:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

The *Convention* states that the interests of human beings are paramount to the interests of science or society (article 2). Article 21 provides:

> **Article 21** – Prohibition of financial gain on human beings
>
> The human body and its parts shall not, as such, give rise to financial gain.

The Committee of Ministers authorized the publication of an Explanatory Report[134] to the *Convention*. The *Report* noted that article 21 is based on the foundational principle of human dignity. It stated that organs and tissues, including blood, should not be purchased and sold or "give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital."[135] However, the *Report* clarified that article 21 does not prohibit the sale of "a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such."[136] Furthermore, it noted that article 21 does not prevent a person from whom an organ or tissue has been removed from receiving compensation, which is distinguishable from remuneration since it only reimburses the person for expenses incurred in donation or any loss of income.

---

[128] U.N. *Convention on Biological Diversity*, Rio de Janeiro, 5 June 1992, available at www.biodiv.org.

[129] HUGO Entics Committee, "Statement on Benefit Sharing" available at http://www.gene.ucl.ac.uk.hugo/beneti.html; Gold and Caulfield, *supra* note 12, at 44.

[130] HUGO, *ibid.*

[131] Council of Europe, *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (DIR/JUR (96) 14) (Strasbourg: Directorate of Legal Affairs, November 1996). Online. http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm. Accessed 2004 [hereinafter referred to as "the *Convention*"].

[132] *Ibid.*

[133] *Ibid.* at article 2.

[134] Explanatory Report, Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, ETS No. 164. Online: http://conventions.coe.int/Treat/en/Reports/Html/164.htm. Accessed September 2004 [hereinafter *Report*].

[135] *Ibid.* at section 132.

[136] *Ibid.* at section 132.

The sale of hair and nails is exempted from article 21 since the *Report* does not consider this activity to be an affront to human dignity. Finally, the *Report* noted that the issue of patents was not considered in connection with this provision and the provision *should not* be interpreted as acknowledging the patentability of biotechnological inventions.

The European Union has adopted its own patent system and rules concerning the grant, enforcement, and definition of patentable subject matter. Member States are bound by these rules, as well as certain international intellectual property and trade agreements. Furthermore, many of these States are signatories to the *European Patent Convention*.[137] The EPC established the European Patent Office ("the EPO") and assigned it responsibility for the granting of patents in each of the signatory countries.

In 1998, the Council of the European Union and the European Parliament adopted *Directive 98/44/EU*[138] in order to bring a measure of harmonization to the European patent system. The *Directive* establishes a set of rules concerning the patentability of biological materials within Member States.[139] The *Directive* clarifies the patentability of certain human and other biological materials for Member States of the European Union.[140] The EPO, as an independent body, is not bound by the *Directive*. However in 1999, certain articles of the *Directive* were incorporated into the EPC rules following a decision of the Administrative Council of the EPC.[141]

It provides that the same general principles of patent law (i.e. only inventions that are new, non-obvious, and have an industrial application are patentable) apply to biological material.[142] Biological material, such as human DNA, that is structurally identical to that found in nature is still patentable as long as it is in a different form than found in nature.[143] The process of isolating and purifying human DNA thus makes it patentable subject matter under the *Directive's* rules. Article 5 states:

> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6 of the *Directive* also contains an *ordre public* and a morality exception for biotechnology patents. In addition, it lists inventions (including processes) that are deemed to be violations of *ordre public* or morality, including cloning human beings, modifying the human germ line genetic identity, and using human *in vitro* embryos for industrial or commercial purposes. Article 6 states:

> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
>
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
>
>   a. processes for cloning human beings;

---

[137] *Convention on the Grant of European Patents*, done at Munich, 5 October 1973 [hereinafter referred to as "the EPC"].

[138] *Directive 98/44/EU of the European Parliament and of the Council*, 6 July 1998. Online: http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html [hereinafter referred to as the *Directive*]

[139] Non-Member States of the European may also fall under the *Biotech Directive* as a result of membership in the EPC or the European Free Trade Association. E.R. Gold & A. Gallochat, "The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lessons for Canada" (2001) The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, online: http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/h_ah00128e.html (date accessed 13 February 2004) [hereinafter referred to as the *Directive*].

[140] Non-Member States of Europe may also fall under the *Directive* as a result of membership in the *European Patent Convention* or the European Free Trade Association.

[141] See, for example, EPC rules 23b, 23c, 23d and 23e.

[142] *Ibid.*

[143] *Directive*, *supra* note 138, at article 3(2).

b. processes for modifying the germ line genetic identity of human beings;

c. uses of human embryos for industrial or commercial purposes;

d. processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

The "*ordre public*" clause provides the basis for concerned citizens to challenge individual patents on the grounds that issuance would be morally offensive.[144] Recently, the EPO announced that it found an invention involving the cloning of a fused human and pig cell to be contrary to morality.[145]

The EPC also allows for third party opposition whereby any person has nine months following the grant of the patent to file an objection. This procedure has been used by public interest interveners, such as Greenpeace.[146] Recently, several public interest groups commenced an opposition proceeding challenging a 1991 EPO grant of a patent covering the synthetic human gene that codes for the human female hormone "relaxin" and another for the hormone itself. The Opposition Division Board, however, upheld the patents and rejected the groups' arguments that the invention lacked novelty and that patenting genes is ethically unacceptable.[147]

The non-binding provisions[148] of the *Directive* also address the ethical issue of informed consent. Recital 26 provides:

> Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.

Lastly, the *Directive* contains two review mechanisms to ensure that it conforms with ethical considerations related to biotechnological innovations.[149] First, the European Commission must make periodic reports to the European Council and the European Parliament on the ethical and research implications of the *Directive*. Second, a group of ethicists will engage in a continuous review of the basic ethical aspects of biotechnology including those in relation to patent law.[150]

6.4.2 The Law in Other Jurisdictions

This section reviews the law respecting the patenting of human bodily materials in three other countries, i.e., the U.S., the UK and Australia. These countries were chosen because they each have a vigorous research and intellectual property sector, and each one has attempted to deal with the issues relating to the patenting of biological materials. Relevant case law from each country has been selected for review to illustrate how the courts have addressed these difficult issues and how they have reshaped the common law to keep pace with changes in biotechnology and social attitudes.

The U.S.

The foundation for patent law is article 1, section 8, clause 8 of the *United States Constitution*. This provision empowers Congress:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries… To make all Laws which

---

[144] J. Chambers, "Patent Eligibility of a Biotechnological Invention in United States, Europe, and Japan: How Much Patent Policy is Public Policy?" (2002) 34 The Geo. Wash. Int'l L. Rev. 223 at 233 [hereinafter *Patent Eligibility of a Biotechnological Invention*].

[145] *Directive, supra* note 138 at 9. See also Q. Schiermeiser, "Germany Challenges Human Stem Cell Patent Awarded 'By Mistake'" (2000) 404 Nature 3-4.

[146] Canadian Biotechnology Advisory Committee, Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee (June 2002) at 7. Online: http//cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html. Accessed June 2004 [hereinafter referred to as the Report].

[147] T. Caulfield, K. Cherniawsky & E. Nelson, "Patent Law and Human DNA: Current Practice" in B Knoppers, T. Caulfield & T. D. Kinsella eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery Publications Limited, 1996) 115 at125.

[148] Europe's obligations under TRIPS require that this provision be non binding. As discussed earlier, TRIPS provides that the only permissible criteria for patentability of an invention are that the invention is new, non-obvious, and has an industrial application, and that the invention is fully disclosed to the public.

[149] *Directive, supra* note 138, at 4.

[150] *Ibid.*

> shall be necessary and proper for carrying into Execution the foregoing Powers and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.[151]

In 1790, Congress passed the first *Patent Act*.[152] The current Act has undergone several subsequent amendments, the most recent being in 1995 and it is codified in Title 35 of the United States *Code*. In the U.S., patent rights do not exist unless they are granted by the federal government. Patents are granted by the U.S. PTO only after an examination is carried out on the patent application and the alleged new invention. If it appears, after examination, that the applicant is entitled to a patent under the law, the Commissioner must grant a patent.[153]

The Act defines the term "invention" as an "invention or discovery."[154] Inventions are patentable if they are a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof… "[155] In addition, to being patentable, they must be non-obvious, and fit within statutorily defined subject matter.[156] Furthermore, the application for a grant of patent must fully disclose and describe "the claimed subject matter so that a person having ordinary skill in the relevant art could make and use the invention."[157]

In 1996, the *Patent Act* was amended by introducing a limited statutory defence to claims of infringement asserted against medical practitioners or health care entities in relation to their undertaking of a "medical activity."[158] The phrase "medical activity" is defined as the performance of a medical or surgical procedure on a body, including a human body, organ or cadaver, or an animal used in medical research directly related to the treatment of humans (35 USC §287(c)(2)(A), (E), (F)). The U.S. medical treatment defence is the only one of its kind in the patent laws of developed nations.

Certain activities are, however, excluded from the defence. One of the excluded activities is the practice of a process in violation of a biotechnology patent. Although the phrase "biotechnology patent" is not defined, it would include the use of isolated genetic materials.[159] There have been recent proposals to extend the scope of the medical treatment defence. One such proposal was contained in the since lapsed Genomic Research and Diagnostic Accessibility Bill 2002. It provided an extension of the definition of medical activity to include the performance of a genetic diagnostic, prognostic, or predictive test.[160] The co-sponsor of the Bill stated that it would have exempted medical practitioners using genetic diagnostic tests from patent infringement remedies.[161]

Case law

Diamond v. Chakrabarty[162] is the landmark 1980 American case dealing with the patentability of the products of biotechnology. Although *Chakrabarty* did not deal with the patenting of human bodily materials, it did determine the scope of the phrase a "composition of matter," in the U.S. *Patent Act*, which is relevant to the patentability of animal and human materials.

In *Chakrabarty*, both the patent examiner and the PTO Board of Appeals rejected a patent application for an invention on the basis that it was a living thing and thus not patentable subject matter under section 101 of the *Patent Act*. The question before the U.S. Supreme Court was whether a live, genetically-engineered micro-organism qualified as either a "manufacture" or a "composition of matter" in the context of the *Patent Act*. A five-person majority of the Court decided that such a micro-organism was patentable under the Act.[163]

Chakrabarty, a microbiologist, made three different patent claims: (1) process claims for the method of producing the bacteria, (2) claims for the inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria, and (3) claims to the bacteria themselves.[164] The patent examiner allowed the first two claims but rejected the patent claim for the bacteria itself on the basis that micro-organisms are products of nature and that living things are not patentable subject-matter under section 101 of the Act.[165] Section 101 of the *Patent Act* states:

---

[151] U.S. Const. art. 1, s.8, cl. 8.

[152] *U.S. Patent Act*, as amended, 35 USC §§ 1-376.

[153] Sheldon W. Halpern, Craig Allen Nard and Kenneth L Port, *Fundamentals of United States Intellectual Property Law: Copyright, Patent, and Trademark* (The Hague: Kluwer Law International, 1999) at 231.

[154] *Supra* note 152, at s. 100.

[155] *Ibid.* at s. 101.

[156] *Ibid.* at ss. 102 and 103.

[157] *Supra* note 153 at 189.

[158] ALRC, *supra* note 14, at 607.

[159] *Ibid.* at 607-08.

[160] Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s.3.

[161] ALRC, *supra* note 14, at 608-09.

[162] *Diamond v. Chakrabarty*, 447 U.S. 303 (U.S. Supreme Court) [hereinafter referred to as *Chakrabarty*].

[163] *Ibid.* at 1.

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Chakrabarty appealed the examiner's decision to the PTO Board of Appeals. The Board concluded that, since Congress had extended patent protection to certain asexually reproduced plants in the 1930 *Plant Patent Act*, section 101 of the *Patent Act* was not intended to cover living things such as laboratory created bacteria.[166]

The case was appealed to the U.S. Supreme Court. It considered the question before it to be one of statutory interpretation of section 101 within the context of the Act. The Court noted that "composition of matter" has been construed in accordance with common usage to include "all compositions of two or more substances and... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."[167] A majority of the Court noted that the legislative history of the *Patent Act* supports a broad construction, and cited from the 1952 Committee Reports on recodifying the Act where Congress stated its intent that statutory subject matter "include anything under the sun that is made by man."[168]

The majority was quick to point out, however, that there are limits to what can be patented under section 101. It noted that the courts have held that the laws of nature, physical phenomena, and abstract ideas are not patentable. A new mineral discovery in the earth or a new plant discovered in the wild is not patentable, neither would have been Einstein's discovery that $E=mc^2$. Quoting from case law, Burger C.J., writing for the majority, noted that these discoveries are "manifestations of... nature, free to all men and reserved exclusively to none."[169]

In the majority's opinion, the living genetically altered micro-organism clearly qualified as patentable subject-matter. The majority noted that the micro-organism was not a naturally occurring organism, but rather was a manufacture or composition of matter a product of human ingenuity with a distinctive name, character and use. The invention had the potential for significant utility, i.e., the breaking down of crude oil.[170]

The argument that living things are not patentable under the *Patent Act* because Congress passed the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act* to specifically patent plants was rejected by the majority. Chief Justice Burger noted that two factors had led to the view that plants were not patentable under the *Patent Act*. First, in 1889, the PTO rejected a patent claim on a fibre found in a plant fearing that it would lead to patents on the trees of the forest and the plants of the earth, which would be unreasonable and impossible. Second, it was considered impossible to provide a sufficient written description of plants to satisfy the requirements of the *Patent Act*.[171]

The majority concluded that there is nothing in the language or the history of the 1939 and 1970 statutes to suggest they were enacted because section 101 of the *Patent Act* was not capable of including living things. Burger C.J. noted that it is Congress and not the courts that define the limits of patentability, but once Congress has spoken:

> ... it is the province and duty of the judicial department to say what the law is... we perform our duty in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose."[172] Chief Justice Burger noted that in this case there is no ambiguity

---

[164] *Ibid.* at 3.

[165] *Ibid.* at 3.

[166] *Ibid.*

[167] *Ibid.* at 4.

[168] *Ibid.*

[169] *Ibid* 5.

[170] *Ibid.*

[171] *Ibid.*

[172] *Ibid.* at 7.

> since the subject-matter statutory provisions were drafted in broad language to fulfil the constitutional and statutory objective of furthering the progress of science and the arts in order that society may realize the attendant social and economic benefits.[173]

Burger C.J. made reference to the risks and fears raised by the petitioner with respect to the granting of patents on living genetically altered organisms. He noted that the Court has been asked to weigh these concerns in making its decision regarding patentability. He wrote:

> … we are without competence to entertain these arguments – either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives… the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[174]

In the majority's view, the risks and concerns raised about patenting genetically altered living materials were matters for Congress and Congress, as the elected body, is responsible for investigating, balancing the competing interests, and amending the statute if necessary.

Ex parte Allen[175] followed on the heels of *Chakrabarty, supra* and *Ex parte Hibberd,*[176] in which the Board of Patent Appeals concluded that non-naturally occurring man-made multicellular plants were patentable under section 101 of the Act. *Ex parte Allen* dealt with whether a non-naturally occurring genetically altered strain of polyploidy oysters (a living multicellular organism) was patentable under section 101 of the Act. The Board of Patent Appeals held that it was patentable, but unfortunately the Board's decision remains unpublished.

Shortly after the decision in *Ex parte Allen, supra,* the PTO issued a notice which stated that:

> The Patent and Trademark Office now considers nonnaturally occurring non-human *multicellular living organisms, including animals,* to be patentable subject matter within the scope of 35 U.S.C. 101… An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law… *A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.* Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection… Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. [emphasis added]

This statement of policy by the PTO was challenged by nine plaintiffs, including the Animal Legal Defence Fund, on the basis that the new rule or policy had been issued in a manner that contravened the public notice and comment requirements. The case, *Animal Legal Defence Fund v. Quigg,*[177] was dismissed by the Court of Appeals for the Federal Circuit on the basis that the plaintiffs lacked standing.

Amgen v. Chugai[178] dealt with appeals and cross appeals involving issues of patent validity, infringement and inequitable conduct regarding two patents. Amgen Inc., owned the patent over purified and isolated DNA sequences that encode erythropoietin ("EP"), as well as host cells transformed or transfected with a DNA sequence.[179] EP is a protein consisting of 165 amino acids which stimulates the production of red blood cells and thus is a useful therapeutic for the treatment of persons with anaemia or blood disorders resulting from defective bone marrow.[180]

---

[173] *Ibid.*

[174] *Ibid.* at 8.

[175] *Ex parte Allen,* 2 U.S.P.Q. 2d (BNA) 1425 (P.T.O. Bd. App. & Int. 1987).

[176] *Ex Parte Hibberd,* 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Int. 1985).

[177] *Animal Legal Defence Fund v. Quigg,* 932 F.2d 920; 1991 U.S. App. LEXIS 7884; 18 U.S.P.Q. 2D (BNA) 1677.

[178] *Amgen v. Chugai,* 927F. 2d 1200; 1991 U.S. App. LEXIS 3481; 18 U.S.P.Q. 2D (BNA) 1016 (U.S. Court of Appeals for the Federal Circuit).

One of the issues before the U.S. Court of Appeals was whether Amgen's patent was valid or whether there had been a prior invention.[181] In reaching its decision, the Court made the following classic statement:

> [a] gene is a chemical compound, albeit a complex one.[182]

Commentators suggest that this is the more appropriate way to treat DNA for purposes of patent law rather than to view it as a source or presenter of information.[183]

The U.S. PTO has issued patents over human DNA sequences, human cell lines, viruses, embryos, fœtuses, embryonic stem cells, animal cell lines (combining animal and human genes), multi-cellular transgenic animals, and human-animal chimeras.[184]

Reports to Government

In 1987, the U.S. Office of Technology Assessment issued a report entitled *New Developments in Biotechnology: Ownership of Human Tissues and Cells*.[185] The Report was requisitioned by two committees of the House of Representatives. It analyzed the economic, legal and ethical rights of the human contributors of tissues and cells, and of the researchers and physicians who obtain these materials and undertake research to turn them into commercially valuable products.[186]

The Report pointed out that any biomedical research and development using human materials rarely results in a profit-making product. In addition, any final product is most likely the culmination of human materials derived from "several individuals."[187] A calculation of the contribution made of any one individual to the final commercial product would be at best speculative.[188]

With respect to property rights, the Report noted that a patent issued by the U.S. government assigns exclusive rights to the patent holder and thus, the patent itself is considered personal property. The Report examined the various elements or property interests in the human body currently recognized by the law, such as the sale of replenishable bodily materials. It concluded that since no area of law definitively sets out the rights of individuals who donate bodily materials for academic or commercial research and since neither the common law nor legislation specifically addresses these questions, it is up to the judiciary to "handle emerging legal questions" by reference to principles and precedents developed for other circumstances, including the law of cadavers, the law of organ transplantation and the law of blood and semen sales.[189]

In 2004, the U.S. President's Council on Bioethics released a pre-publication version of its report entitled, *Reproduction and Responsibility: The Regulation of New Biotechnologies*.[190] The Report focused on biotechnology and assisted human reproduction, human genomic knowledge, and human embryo research. It contained a set of policy recommendations with respect to biotechnology for the U.S. President, but fell short of recommending federal oversight and regulation of these activities, in part because of the very controversial nature of the issues and the lack of consensus in American society.[191]

The Report noted that to date patents have been issued in the U.S. for modified human tissue and cell lines, as well as human DNA molecules. In the view of the authors, the grant of a patent created "a quasi property right" and the notion that a person might own a part of another person raised "deep worries."[192] The Report also made reference to the positive aspects associated with a patenting regime, especially the fostering of continued research, which has the potential to ultimately benefit the public. It recommended that Congress permanently amend the patent laws to prohibit the patenting of human embryos, or a human organism at any stage of development, and that Congress enact restrictions on the patenting of human gametes. It made no recommendations, however, regarding the patenting of other human bodily materials.[193] (Note that none of the recommendations have been implemented.)

---

[179] *Ibid.* at 1-2.

[180] *Ibid.* at 2.

[181] *Ibid.* at 4.

[182] *Ibid.*

[183] R. Stephen Crespi, "Patenting and Ethics: A Dubious Connection" (2001–02) 5 Bio-Science L. Rev., at 75.

[184] Cyril R. Vidergar, "Biomedical Patenting: Permitted, But Permissible?" (2002) 19 Santa Clara Computer & High Tech. L.J. 253, at 261; see also Stacy Kincaid, "Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research" (2003) 30 Pepp. L. Rev. 553, at 561.

[185] U.S. Office of Technology Assessment, *New Developments in biotechnology: Ownership of Human Tissues and Cells* (Washington, D.C.: U.S. Government Printing Office, 1987).

[186] *Ibid.* at iii.

[187] *Ibid.* at 55.

[188] *Ibid.*

[189] *Ibid.* at 86-7.

[190] President's Council on Bioethics, *Reproduction and Responsibility: The Regulations of New Biotechnologies* (Pre-Publication Version) (Washington, D.C.: President's Council on Bioethics, 2004).

[191] *Ibid.* at xvii.

The UK

In the UK, a patent application can be made to the national patent office ("PO") and/or to the EPO, by virtue of the UK's membership in the European Patent Organization. If the applicant only seeks patent protection in the UK, then he or she is only required to apply under the UK *Patents Act 1977* (as amended by the *Patents Act 2004*).[194] If, however, the applicant desires patent protection in a number of European countries, then it may be more efficient to apply to the EPO for a European patent.[195]

The UK *Patents Act* states in section 1 that to be patentable an invention must be new, involve an inventive step, be capable of industrial application, and not otherwise excluded under subsections 2 and 3. These subsections exclude from patentability: (1) a discovery, (2) an invention which would encourage offensive, immoral or antisocial behaviour, and (3) any variety of plant or animal or any biological process for the production of animals or plants (excluding micro-biological processes or their products). The phrase in section 1(2) "among other things" has been interpreted to mean that the list of excluded subject matter is not exhaustive and can be added to through case law.[196]

The *European Patent Convention*[197] has been ratified by the UK. A European patent is generally to be treated in the UK, or any other signatory to the *Convention*, in the same manner as a patent granted under domestic patent legislation. In effect, a European patent creates a series of parallel national patents, which are treated as if they originated from each national patent office of the designated state.[198] The *Convention* established the European Patent Organization which administers the EPO and an Administrative Council. The task of the European Patent Organization is to grant European patents through the EPO, which is supervised by the Administrative Council.

To be patentable under the *Convention*, an invention must be new, capable of industrial application, and involve an inventive step (article 52). Article 52 lists those items that are not considered inventions, including discoveries and presentations of information. In addition, surgical methods for treating the human or animal body, as well as therapy and diagnostic methods performed on the body are not patentable as inventions. However, substances or compositions used in these methods are patentable.

At the time of writing, the UK's *Human Tissue Bill* is currently before the House of Lords. Section 1 of the Bill would authorize certain activities related to the body of a deceased person or to excised bodily materials from a deceased or a living person, such as storage and use. In order to undertake certain activities, such as research using bodily materials, the researcher would have to obtain a licence and ensure that the proper consents have been obtained (s. 16(2)(c) and (e) and Schedule 1, Part 1, s. 6). The Bill would establish the Human Tissue Authority which has responsibility for licensing, preparing codes of practice and enforcing the Bill.

Section 32 of the Bill prohibits commercial dealings in human material intended for transplant. The Bill does not, however, contain any provisions to explicitly prohibit the payment of consideration in exchange for human bodily materials donated for research purposes. Furthermore, there does not appear to be another statue in the UK that expressly prohibits the payment for donations of human materials for research purposes.

Case law

In 1926, *Commercial Solvents v. Synthetic Products*[199] approved the first grant of a UK patent for a bacteriological process which used live bacteria to produce acetone.[200] Although *Commercial Solvents* confirmed the validity of a patent over a bacteriological process, the UK PO continued to refuse to grant patents for living organisms themselves, such as plants or bacteria.

---

[192] *Ibid.* at 160.

[193] *Ibid* at 181 and 202.

[194] *Patents Act 1977*, c. 37, as amended by the *Patents Act 2004*, c. 16.

[195] Young, et al., *supra* note 2 at 32.

[196] *Ibid.* at 16.

[197] *European Patent Convention*

[198] Nuffield Council of Bioethics, *supra* note 3, at 15.

[199] *Commercial Solvents v. Synthetic Products* (1926), 43 R.P.C. 185 [hereinafter referred to as *Commercial Solvents*].

In *General Electric Co., Ltd.'s Application,*[201] the Superintending Patent Examiner rejected an application for a patent over a process for artificially inducing mutations in micro-organisms using electric shock treatment. The rationale being that the process resulted in "artificial mutants of living organisms not specifically associated with manufacturing processes" and thus the process claimed was not considered an invention within the meaning of s. 101 of the UK *Patents Act.*[202] In reaching his decision the Superintending Patent Examiner wrote:

> I feel that the [Patent] Office, on the whole, has acted liberally in construing "manufacture" to include living matter, even though of a low order… I feel… that this should be the limit of construction of "manufacture" in this field, for I think that it is straining the term too far to include therein artificial mutants of living organisms not specifically associated with manufacturing processes.[203]

The appeal was dismissed by the Patents Appeal Tribunal. In reaching its decision, the Tribunal observed:

> This appeal illustrates one more facet of the difficult problem of the content of the expression "manner of manufacture" and is in part made more difficult because of the employment in the process of living organisms. A long established Patent Office practice has prevented the acceptance of claims directed to the treatment of the more advanced forms of life, a practice applied substantially by rule of thumb methods, derived from a time when the many gradations of living forms were not as fully appreciated as is now possible… In consequence Hearing Officers have apparently been disposed to seek some dividing line by which a division between higher and lower forms of living matter could be drawn with precision and thus to render the "rule" more convenient of application.[204]

In the Tribunal's opinion, there was no advantage in adopting any other test than what is provided in the Act. The Tribunal held that the process disclosed was not a manner of manufacture and thus was not patentable.[205]

The approach of the UK PO had been that a "manufacture" could not include living things or methods involving the treatment of living organisms. In 1973, however, the High Court in *American Cyanamid v. Berk Pharmaceuticals, Ltd.*[206] held that the subject-matter of the patent, a process using mutant strains of Streptomyces aurerfaciens to produce the antibiotic tetracycline, was an invention under the Act. The Court was urged to adopt the position that the *Patents Act* was not of "sufficient breadth" to cover a process involving a micro-organism and if such protection was to be granted over this process, it was up to Parliament to pass new legislation.[207] The Court, however, rejected that argument and held that the process at issue was a process intimately associated with trade and manufacture.[208] The UK PO has since issued patents over microbacterial strains, mutants and isolates of naturally occurring strains.

Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.[209] dealt with questions of patent infringement and patent validity under the UK *Patents Act* and the EPC. In 1984, a patent was granted to Kirin Amgen for:

> … a DNA sequence for use in securing expression in a prokaryotic or eukaryotic host cell of a polypeptide product having at least part of the primary structural configuration of that of a erythropoietin to allow

---

[200] *Re Application of Abitibi Co.* (1982) 62 C.P.R. (2d) 81 at 3 (Patent Appeal Board and Commissioner of Patents) [hereinafter referred to as *Abitibi*].

[201] *General Electric Co. Ltd.'s Application* [1961] R.P.C. 21 (Superintending Patent Examiner) [hereinafter *General Electric*].

[202] *Ibid.* at 23.

[203] *Ibid.* at 22-23.

[204] *Ibid.* at 25.

[205] *Ibid.*

[206] *American Cyanamid Co. v. Berk Pharmaceuticals Ltd.*, [1973] F.S.R. 487 (High Court of Justice — Chancery Division) [hereinafter referred to as *American Cyanamid*].

[207] *Ibid.* at 512.

[208] *Ibid.* at 513.

[209] *Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.* [2002] EWCA Civ. 1096 (Supreme Court of Judicature Court of Appeal (Civil Division)) (Lexum) Online: http://www.courtservice.gov.uk/judgmentsfiles/j1329/Kirin_v_Hoechst.htm [hereinafter referred to as *Kirin*]

> possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and to increase haemoglobin synthesis or iron uptake.[210]

As noted in the U.S. case *Amgen, supra*, EP is a protein that serves to regulate the body's production of red blood cells, which transport oxygen from the lungs to every tissue in the body. The inventor identified and located the nucleotide sequences that codes for human EP and, using genetic engineering techniques (recombinant DNA technology), produced substantial amounts of EP.[211] EP is important for use in both diagnosis and the treatment of human blood disorders. The U.K. and EPC patent was granted over both the process and the product.[212]

One of the issues before the Court of Appeal concerned the manner in which the inventor's work had been patented. The Court referred to article 5 in the *Directive* which states:

> 1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
>
> 2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The Court noted that the EPO allows claims for products defined in terms of a process of manufacture; however, the product still must meet the criterion of patentability. Hoechst maintained that to be valid, the invention must be new and, in the case of a product-by-process claim, the claim can only be new if the product itself is new. In this case, Hoechst argued that the product was an "old article."[213]

The Court noted, however, that the *Directive* permits claims to biological elements as long as they are "isolated or otherwise produced by means of a technical process even if the structure of that element is identical to that of a natural element."[214] In the Court's view, the *Directive* clearly intended to cover biological elements such as polypeptides produced by a process. The Court of Appeal concluded that the patent was valid and had not been infringed.

Reports to Government

In July 2002, the Nuffield Council on Bioethics (the "Council") issued a discussion paper entitled, *The ethics of patenting DNA: a discussion paper*.[215] The Council was jointly funded by the UK Medical Research Council, the Nuffield Foundation and the Wellcome Trust. In 2000, it convened a group of experts (academics, lawyers, ethicists) to discuss the various ethical and social issues related to patenting DNA with the objective of producing a discussion paper, conclusions and recommendations, and ultimately fostering further discussion.[216] The *Paper* provides a detailed review of the patent system, explains human DNA and patenting, provides case studies, undertakes a discussion of the issues, and arrives at conclusions and recommendations to modify the patent system and to mitigate, what the authors considered, the "deleterious effects of patents" already granted.[217]

The *Paper* concludes that, with respect to the patenting of human genes, there is an insufficient degree of both "inventiveness" and "utility" to warrant the grant of a patent. In the future, the granting of patents over genes should become the exception rather than the norm.[218] The Council notes that the description of an association between a gene and a human disease is in reality a discovery. It writes that:

> ... allowing property rights to be asserted over all uses, or even all diagnostic uses, of DNA sequences in relation to diagnostic tests gives inventors too great a

---

[210] *Ibid.* at 18.
[211] *Ibid.* at 4.
[212] *Ibid.* at 15.
[213] *Ibid.* at 20.
[214] *Ibid.* at 22.
[215] Nuffield Council on Bioethics, *supra* note 3.
[216] *Ibid.* at v.
[217] *Ibid.* at 69.
[218] *Ibid.* at 69-70.

> monopoly in the light of the contribution and inventiveness of their product, may hamper innovation and may not, in fact, satisfy the legal criterion for patenting … [and] if left unchanged, will have a deleterious effect on the development and use of such tests.[219]

The Council recommends that the U.S. PTO, the EPO and the Japan Patent Office examine ways to more stringently scrutinize patent applications over DNA sequences for use in diagnosis.[220] It also recommends that these three patent offices consider limiting the scope of product patents, which assert rights over naturally occurring DNA sequences, to only the uses specified in the patent claims.[221] The Council also recommends that the granting of patents over gene fragments or partial sequences (such as an SNP or an EST) as research tools be discouraged.[222]

Australia

The *Australian Constitution* grants authority over intellectual property, including patents, to the Commonwealth Parliament. Pursuant to this authority, Parliament enacted the *Patents Act 1990* (Cth) and the *Patents Regulations 1991* (Cth) to govern patenting.

The Act establishes a Commissioner of Patents who has authority to grant a patent, upon application and examination by the Patent Office ("PO"). IP Australia, a branch of the Department of Industry, Tourism and Resources, has developed a *Patent Manual of Practice and Procedure* (the *Manual*) to assist patent examiners in applying the Act and Regulations. An applicant can apply for either a standard or an innovation patent. The latter form of patent would be granted for inventions and would have to meet the requirements of the TRIPS Agreement.[223]

Under section 18 of the *Patents Act 1990*, an invention may be patented if it: (1) is a manner of manufacture, i.e., appropriate subject-matter for a patent, (2) is novel, (3) involves an inventive step, (4) is useful, and (5) has not been secretly used in Australia prior to filing for patent protection. Section 18(2) excludes from patentability both human beings and the biological processes for their creation. This section has not yet been judicially interpreted and thus its scope remains uncertain.[224] The *Manual*, however, provides that the following are included in section 18(2): (1) human beings, fœtuses, embryos or fertilized eggs, (2) methods of *in vitro* fertilization or cloning methods for creating a human being, and (3) wholly biological processes (beginning with fertilization and ending with birth) to create a human being. The *Manual* also provides that section 18(2) does not apply to human genes, tissues and cell lines and thus they can be patented. Whether section 18(2) applies to human stem cell lines and stem cell technologies is not clear and this has been the subject of debate.[225]

Standard patents may be granted for plants and animals and for the biological processes that result in their creation.[226] Section 18(4) provides that microbiological products and processes are patentable.

An application for a standard patent can be refused where the Commissioner of Patents considers it would be contrary to law (s.50 (1) (a)). The *Manual* suggests that the Commissioner's discretion under this provision should be exercised only in the clearest of cases, and only where the "use" of the patent would be unlawful and there is no alternative lawful use described in the application.[227]

In Australia, genetic materials and related technologies are currently treated as "inventions" for which patent protection can be granted under the Act. The term "invention" is defined in the Act as:

> Any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.

---

[219] *Ibid.* at 70.

[220] *Ibid.*

[221] *Ibid.* at 73-4.

[222] *Ibid.* at 71.

[223] ALRC, *Final Report* (Genes and Ingenuity: Gene Patenting and Human Health) (Sydney: The SOS Printing Group Pty Ltd., 2004) at 94-96.

[224] *Ibid.* at 177.

[225] *Ibid.*

[226] *Ibid.* 176.

[227] *Ibid.* at 177-8.

On July 13, 2004, the Australian Deputy Commissioner of Patents decided a patent application for a culture medium and a method of growing pre-blastocyst human embryos.[228] The Deputy Commissioner rejected the claim to the method of growing pre-blastocyst human embryos on the basis of section 18(2) of the *Patents Act 1990*. It excludes human beings and their biological processes for generation from patentability.[229]

The applicant argued that a human being was created at fertilization and since the method claimed was subsequent to fertilization, it was not subject to section 18(2) of the Act.[230] The Deputy Commissioner considered that the method of generation claimed by the applicant was one step on the path to generating a human being. The term "process" in section 18(2) applies to biological processes from fertilization to birth as long as it is related to the generation of a human being. These processes include: fertilizing an ovum, cloning at the 4-cell stage by division and cloning by replacing nuclear DNA (reproductive cloning).[231]

Case law

The Australian courts have held that to determine the meaning of "invention," a policy-oriented approach should be adopted. In *National Research Development Corporation v. Commissioner of Patents*,[232] the issue before the Commissioner was whether a process for killing weeds could be considered an "invention" for the purposes of the *Patents Act 1990*. The High Court noted that in determining whether a process or a product is patentable, it would be a mistake to limit one's thinking that manufacture was limited to the notion of producing only tangible goods either by hand or machine. Instead, the Court noted that the word "manufacture" is not intended to be literally applied to a question of patentability, but is simply a "general title" in the Statute of Monopolies for the entire category under which all grants of patents made in accordance with principles of patent law must be subsumed.[233]

The Court held that the correct question to ask was whether this is a proper subject of letters patent according to the principles developed for the application of section 6 of the *Statute of Monopolies*. This, in the Court's view, was a very different question. A review of those principles demonstrated that what comes within the term "manufacture" has evolved over time. The Court cautioned against giving the term an exact meaning:

> To attempt to place upon the idea [manufacture] the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.[234]

The Court concluded that for an "invention" to be a "manner of manufacture," it must belong to the useful arts rather than the fine arts, it must provide a material advantage and its value to the country must be in the field of economic endeavour.[235] With respect to the case before it, the High Court concluded that it was dealing with "a process producing its effect by means of a chemical reaction" resulting in a weed-free, or comparatively weed-free condition of the farm land and as such, it is properly described as a process.[236] The Court allowed the appeal and held that the process is properly the subject-matter of a patent under the Australian *Patents Act 1990*.[237]

The distinction between an invention and a discovery has arisen in the area of patent applications over genetic sequences. IP Australia's *Manual* noted that it is not possible to distinguish between a discovery and an invention. This issue first arose with respect to patent applications for micro-organisms. In *Ranks Hovis McDougall's Application*,[238] the Commissioner of Patents had to decide whether a genetically altered micro-organism was a discovery or an invention. In holding that the micro-organism was an invention, the Commissioner noted:

---

[228] Decision of A Deputy Commissioner of Patents regarding Patent Application 44916/99 in the name of Luminis Pty and Fertilitescentrum AB, and a proposed direction under s. 107 to delete certain claims, Issued 13 July 2004.

[229] *Ibid.* at 1.

[230] *Ibid.* at 1-2.

[231] *Ibid.* at 9-10.

[232] *National Research Development Corporation v. Commissioner of Patents* (1961) R.P.C. 135.

[233] *Ibid.* at 142.

[234] *Ibid.*

[235] *Ibid.* at 146.

[236] *Ibid.* at 147.

[237] *Ibid.*

[238] *Ranks Hovis McDougall's Application* [1976] 46 AOJP 3915 [hereinafter referred to as *Ranks Hovis*].

> An objection that a claim to a new microorganism, being something living, is not a manner of manufacture is based, in my opinion, on too restricted a view of the meaning of manufacture in section 6 of the Statute of Monopolies.[239]

Since the decision in *Ranks Hovis*, the Australian PO has granted patents on newly created micro-organisms.[240]

The courts in Australia have had few opportunities to consider whether genetic materials and technologies fall within "manner of manufacture." IP Australia's *Manual* provides that the building blocks of living matter, including human DNA, which have been identified and copied from their natural source and reproduced synthetically as unique materials for a specific industrial use are not to be considered as discoveries for the purposes of the Act.[241] The *Manual* also provides guidance on the difference between a discovery and an invention in the case of gene patents:

> The discovery of a micro-organism, protein, enantiomer or antibiotic in nature can be claimed in its isolated form or as substantially free of (perhaps, unspecified) impurities. Also, a gene can be claimed as the gene *per se* (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene.[242]

Reports to Government

In 2002, the Australian government, concerned with the rapid advances in human genome research and genetic and related technologies, referred a number of questions to the Australian Law Reform Commission ("the ALRC") for inquiry and report. The terms of reference required the ALRC to, for example, examine and report back on "... the impact of current patenting laws and practices including licensing related to genes and genetic and related technologies on the conduct of research and its subsequent application and commercialisation."[243]

The ALRC's report, entitled *Genes and Ingenuity: Gene Patenting and Human Health* (the "Final Report"), was submitted to Parliament on August 31, 2004. In preparing the Final Report, the ALRC undertook extensive public consultations through the release of an "issues and discussion" paper for public comment.

The Final Report is quite comprehensive, covering topics that range from an overview of the history of patents to the patentability of genetic materials and technologies to challenging and enforcing patent rights. The terms of reference asked the ALRC to suggest changes that might be required of the Australian patent regime to address any problems, "... with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies."[244]

In chapter 22 of the Final Report, the ALRC notes that there is some evidence that gene patents may, in the future, have an adverse effect on healthcare. The concern is that the exclusive licensing of patents over medical genetic tests will result in adverse effects with respect to cost, access, quality of the test, and innovation with regards to the development of new or improved testing techniques.[245]

The Final Report considers that one of the single most important concerns is the effects on research of patents on genetic materials or technologies that are used as research tools.[246] This is especially the case with respect to patents over research tools such as ESTs and SNPs and other isolated genetic materials. Some research tools may be categorized as "foundational" or "upstream" research tools. The following statement included in the Final Report captures the concern with patents over foundational research tools:

> The area covered by these patents is at the cutting edge of research. The owners have the power to limit or extend the amount of research done. By their selectivity

---

[239] *Ibid.* at 3918.
[240] *Abitibi, supra* note 200, at 5.
[241] ALRC, *supra* note 223, at 129.
[242] *Ibid.* at 129.
[243] *Ibid.* at 9-10.
[244] *Ibid.* at 28-29.
[245] *Ibid.* at 605.
[246] *Ibid.* at 355.

in granting licences, they may slow, or even halt, the discovery of further beneficial mechanisms.[247]

The Final Report recommends changes to the PO practice with respect to some research tools, such as ESTs. In addition, if these problems cannot be resolved by exercising current remedies, reform options to the address the impact of these patents would have to be undertaken. The Final Report notes that problems could be addressed through the use of the compulsory licensing and Crown use and acquisition provisions of the *Patents Act 1990*.[248]

Proposal 13-1 of the Final Report states that principles and guidelines should be developed by the Australian Research Council and the National Health and Medical Research Council to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.[249]

6.4.3 Canada

The *Patent Act*

Section 91(22) of the *Constitution Act, 1867* assigns Parliament the exclusive legislative authority for "Patents of Invention and Discovery." In 1870, the federal government passed it first *Patent Act*. It authorized the creation of the Patent Office ("PO"), which is an agent of Industry Canada. The PO is part of the Canadian Intellectual Property Office ("CIPO"). The CIPO is responsible for patents and other forms of intellectual property, including trade-marks and copyright.[250]

Canadian patents may be granted by the Commissioner of Patents for new inventions (process, machine, manufacture, composition of matter), or any new and useful improvement of an existing invention. In order to be patentable, the invention must be new (first in the world), useful (functional and operative), and non-obvious to someone skilled in that area.[251] Patents will not be granted for a scientific principle, a method of doing business, a computer program or a method of medical treatment.[252] The Commissioner will not grant a patent for a "higher" life form, such as a seed, whole plant or animal. Since 1982, however, the Commissioner has granted patents over "lower" life forms, such as micro-organisms, fungi and single cells.

The *Patent Act*, unlike the EPC, the European *Directive*, and the UK *Patents Act*, does not contain an *ordre public* and morality exception to patentability. Previous versions of the Canadian Act contained a provision which exempted from patentability inventions for illicit objects. It was removed as part of a package of legislative amendments intended to bring the statute into compliance with the provisions of the NAFTA.[253] As a result, Canadian patent law does not provide the Patent Commissioner with discretion to exempt on the basis of morality.[254] The Act does, however, require that the grant of a patent be in accordance with the law. Section 40 provides that where the Commissioner is of the view that an applicant is not "by law" entitled to be granted a patent, he or she must refuse the application.

Case law

In 1982, the Canadian PO faced a similar claim to that considered by the U.S. Supreme Court in the 1980 case of *Chakrabarty, supra*. In *Abitibi*,[255] the Commissioner of Patents was asked to grant a patent over a genetically engineered life form, i.e., a mixed fungal yeast culture system.

In *Abitibi*, the Patent Appeal Board noted that the patent examiner had granted a patent to Abitibi Co. for the process biodegrading spent sulfite waste liquor from the manufacture of wood-pulp, but had refused to grant a patent for the product a microbial culture system acclimatized to spent sulphite liquor and having five principal fungi components. The application for a patent over the product was rejected because "living or viable matter" was not considered patentable since it could not be considered either a "manufacture" or a "composition of matter" under section 2 of the Act.[256]

---

[247] RNA-mediated interference is the inhibition of expression of specific genes by double stranded RNA (ds RNA): E Milward and others, *Submission P46*, 20 October 2003; ALRC at 357.

[248] ALRC, *supra* note 223, at 372.

[249] *Ibid.* at 375.

[250] Canadian Intellectual Property Office, *A Guide to Patents* (Hull, Quebec: Canadian Intellectual Property Office, 2000) at 3.

[251] *Ibid.* at 3.

[252] *Ibid.*

[253] The wording of the previous provision exempting products from patentability under the *Patent Act* was: "an invention that has an illicit object in view."

[254] *Supra*, note 146, at 6.

[255] *Abitibi, supra* note 200.

The Appeal Board reviewed the relevant case law from other jurisdictions dealing with the patenting of living materials. The long-standing approach of the PO had been that living materials were not patentable. The decision in *Chakrabarty, supra,* however, was now seen as casting uncertainty on that position, since the U.S. Court concluded that the terms "manufacture" and "composition of matter" could extend to micro-organisms as products of "human's ingenuity having a distinctive name, character and use."[257]

The Appeal Board noted that technological advances have led patent offices around the world to alter their interpretation of statutory subject-matter in order to adapt to the new industrial realities. The Board recommended that the patent examiner's objections to patentability of fungi products be withdrawn. It recognized that the decision would have far reaching impacts, extending patentability to:

> … all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds… and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.[258]

The Board observed that there were no reasons for distinguishing between life forms when deciding the issue of patentability. It did, however, note that whether higher life forms, such as animals and plants, should be patented is debatable. In any event, it doubted whether an inventor of a higher life form could reproduce it at will and in a consistent fashion, since more complex life forms tend to have less consistency between individual members. If, however, an inventor was able to achieve consistency and all the other criterion of patentability were met, then the Appeal Board could not see why such an invention should be treated any differently.[259]

In *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents),*[260] the Supreme Court of Canada was asked whether a new variety of soybean plant was patentable. The PO Examiner had refused Pioneer Hi-Bred's application for a patent over the plant, the pod and the seed. The reasons for refusal were based on the Examiner's view that the new plant did not fit within the definition of "invention" in section 2 of the *Patent Act* and on the PO practice of considering as non-patentable a process and a product that is a new genetic strain or variety of plant or animal.[261] Pioneer Hi-Bred appealed to the Patent Appeal Board which upheld the Examiner's decision and noted that the new plant variety did not qualify as a "manufacture."[262]

The Federal Court of Appeal ruled against Pioneer Hi-Bred finding that the new plant variety did not fit within the term "invention" in section 2 of the Act and that Pioneer Hi-Bred had not met the disclosure requirements of the Act.[263] The Supreme Court examined whether a new variety of soybean produced through artificial cross-breeding qualified under the *Patent Act* as an invention. The Court stated that the real issue is whether a form of life can be patented.

Pioneer Hi-Bred argued that the level of human intervention required to create this new plant variety allowed it to qualify for patent protection. The Court disagreed, holding that since the intervention by Hi-Bred did not in any way alter the soybean reproductive process, which follows the laws of nature, the process could not be the basis for a patent. Furthermore, the Supreme Court agreed with the Court of Appeal that Hi-Bred's depositing of seeds was not sufficient to satisfy the requirements of disclosure under the Act. Finally, the Court noted that since the *Patent Act* does not contain any provisions relating to biotechnological inventions and new forms of life, the new soybean plant variety is not currently patentable.[264]

---

[256] *Ibid.* at 2-3.
[257] *Ibid.* at 5.
[258] *Ibid.* at 6.
[259] *Ibid.* at 6-7.
[260] *Pioneer Hi Bred Ltd. v. Canada (Commissioner of Patents)* (1989) 25 C.P.R. (3d) 257 (Supreme Court of Canada) (Lexis — CPR) [hereinafter referred to as *Pioneer*].
[261] *Ibid.* at 3.
[262] *Ibid.*
[263] *Ibid.* at 4.
[264] *Ibid.* at 9.

In *Harvard College v. Canada (Commissioner of Patents)*,[265] the Supreme Court of Canada was asked to determine whether the words "manufacture" and "composition of matter" in s. 2 of the *Patent Act* were broad enough to include higher life forms. Harvard College applied for a Canadian patent on both the process used to create its oncomouse and on the mouse itself. The Patent Examiner issued a patent for the process but refused to issue a patent for the oncomouse, on the basis that it was not an invention under the Act. Harvard College appealed the Examiner's decision to the Commissioner of Patents, who upheld the decision. The Trial Division of the Federal Court dismissed the College's appeal. The Federal Court of Appeal, however, allowed the College's appeal. The Commissioner of Patents appealed the decision to the Supreme Court of Canada.[266]

The five member majority of the Supreme Court considered that the key to the patentability of biological materials, including human materials, was to be found in the Act's definition of "invention." Using the principles of statutory interpretation, the majority considered that the terms "manufacture" and "composition of matter" were not capable of including animal and plant life."[267]

Justice Bastarache, writing for the majority, was of the view that the oncomouse could not easily be considered either a 'manufacture' or a 'composition of matter'."[268] These terms, used to define "invention," were not broad enough by the majority to include higher life forms. In the majority's view, human and animal life were more that mere compositions of matter. Furthermore, the majority opined that a patent over a higher life form would represent a significant increase in the scope of patent rights because higher life forms reproduce on their own, without human intervention, and any patent would thus be extended to the progeny. This increase in scope would not have been in keeping with the scope of patent rights granted in other fields.[269] The majority concluded that Parliament did not therefore intend the patenting of higher life forms.

An alternate view of the legislative scheme respecting patentability is found in the dissent. It interpreted the legislative scheme as permissive rather than restrictive. Justice Binnie, writing for the dissent, pointed out that Parliament, in 1993, indicated that value judgements have no place in decisions regarding patentability when it did not take the opportunity to amend the *Patent Act* to grant discretion to refuse patents on the basis of *ordre public* or morality. If an invention meets the criterion of patentability, i.e., useful, non-obvious and novel, the Commissioner must grant a patent. Justice Binnie noted that all of the distinctions or "proposed dividing lines" between different life forms for the purpose of determining whether a "composition of matter" is an invention and thus patentable, are misguided. Neither the Act nor the jurisprudence respecting patentability contemplated or provided a distinction between higher and lower life forms. Thus the distinction was merely an "invention of the PO," to narrow the definition of 'invention' to reflect policy positions.[270] This view of the legislative scheme confirmed that decisions respecting patentability made on the basis of morality or ethics have no place under the Act.

The dissent considered that section 40 of the Act was the only provision under which the Commissioner was granted discretion to reject a patent application. Binnie J. noted that the phrase "by law" in section 40 refers to more than just the *Patent Act* and would presumably include other legislation, as well as the *Charter* and the common law. He pointed to the common law principle that people cannot own other people to resolve the question of whether a human being could be considered as a patentable "composition of matter" for the purposes of the Act. If that principle was not sufficient, he suggested relying on sections 7 and 15 of the *Charter*. In his view, this question would not even arise under the *Patent Act* since it is addressed by these other laws.

The dissent held that:

> … the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human

---

[265] *Harvard College v. Canada (Commissioner of Patents)* [2002] SCC 76. Online: LEXUM. <http://www.lexum.umontrreal.ca/csc-scc/cgi-bin/disp.pl/en/pub/2002/vo14/html/2002scr4> [hereinafter referred to as *Harvard Mouse*].

[266] *Ibid.* at 2.

[267] *Ibid* at para. 120.

[268] *Ibid* at para. 155.

[269] *Ibid* at para. 170.

[270] *Ibid* at para. 47.

> modification of the genetic material of which it is composed, is an inventive 'composition of matter' within the meaning of section 2 of the *Patent Act*.[271]

Justice Binnie noted, however, that a patent does not give the inventor *carte blanche* to practice the invention free from government imposed regulatory controls.[272] The dissent considered that the oncomouse was patentable subject matter.[273]

It is interesting to note that both the majority and minority in *Harvard Mouse* observed in *obiter* that a fertilized, genetically altered mouse egg would be patentable subject matter.[274] The majority considered it an invention under the *Patent Act*, while the dissent would presumably have found it to be patentable subject matter unless otherwise excluded under section 40.

The case of *Monsanto Canada Inc. v. Schmeiser*[275] involved questions of patent infringement and scope. In 1993, Monsanto was granted a patent for genetically engineered genes and for cells containing those genes which when inserted into plants, such as canola, increased their tolerance to herbicides containing glyphosate. Fields planted with canola seed containing the patented gene could be sprayed with glyphosate herbicides, which killed any weeds, while leaving the canola plants undamaged. Farmers wishing to grow Roundup Ready Canola had to obtain a licence from Monsanto. Under the licence, the farmer could use the seed to plant a single crop and could sell that crop for consumption, but only to a purchaser authorized by Monsanto. The farmer could not sell or give the seed to a third party, or save the seed for replanting or inventory.[276]

Mr. Schmeiser never purchased Roundup Ready Canola. His farm was located in an area of Saskatchewan in which five farmers had switched to Monsanto's genetically modified canola. In 1998, Monsanto obtained a court order to conduct tests on Mr. Schmeiser's canola crop. The results showed that 95 to 98 percent of his 1,000 acres of canola crop was composed of Roundup Ready plants. Mr. Schmeiser claimed that the seeds had simply blown onto his land from the adjacent farms. The seeds grew into plants from which he collected the seeds and used them to replant his fields the following year.

The trial judge found that Monsanto's patent was valid. With respect to patent infringement, the trial judge found that Mr. Schmeiser knew or ought to have known that he had saved and planted seed containing the patented gene and cell, and he had sold the resulting crop. In other words, Mr. Schmeiser had infringed Monsanto's patent. The Federal Court of Appeal confirmed the trial court's finding with respect to Mr. Schmeiser's infringement of the patent, but did not comment on the patent's validity.[277]

The case was appealed to the Supreme Court of Canada. A five member majority of the Court adopted an expanded view of the *Patent Act's* legislative scheme with respect to questions of infringement. It is interesting to note that the majority in *Monsanto* was composed of some of the same members who had been part of the dissent in *Harvard Mouse*. The majority identified the following issues: (1) whether Mr. Schmeiser's acts of saving, planting, harvesting and selling the crop containing the patented gene and plant cell constituted a "use" of Monsanto's invention contrary to the *Patent Act*, and (2) whether Mr. Schmeiser used the patented invention in commercial or business interests.

The majority decision was coauthored by Chief Justice McLachlin and Justice Fish. The majority stated that it would decide the case by applying the established principles of patent law to the facts before it.[278] At the outset, the majority noted that it was not concerned with the scope of the patent granted to Monsanto nor with questions as to the wisdom of patenting genetically modified cells and genes, rather those were matters falling within the purview of Parliament. Although the majority expressly stated that its decision was not with respect to the scope of Monsanto's patent,[279] its approach of applying patenting principles established in the manufacturing context to biological materials arguably had the effect of expanding the scope of the patent for the purposes of infringement. The majority applied the following principle:

---

[271] *Ibid.* at para. 8.

[272] *Ibid.* at para. 4.

[273] *Ibid.* at para. 115.

[274] *Ibid.* at paras. 3 and 162.

[275] *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902. Online: http://www.lexum. Umontreal.ca/csc-scc/cgi-bindisp.pl/en/rec/html/2004scc034.wpd.htm. [hereinafter referred to as *Monsanto*]

[276] *Ibid.* at para. 11.

[277] *Ibid.* at 2.

[278] *Ibid.* at paras. 2 and 3.

[279] *Ibid.* at para. 2.

> [W]here a defendant's commercial or business activity involves a thing of which a patented part is a significant or important component, infringement is established. It is no defence to say that the thing actually used was not patented, but only one of its components.[280]

By applying this principle to the facts of the case, the majority found that Mr. Schmeiser's unlicensed collecting, saving, planting of the seed (containing the altered gene), and his harvesting of the resulting crop (containing the patented gene and cell) to his advantage constituted "use" and thus an infringement of Monsanto's patent.[281] Monsanto's patent covered processes, including the method of regeneration, the chimeric genes, and the modified cells. Monsanto was not seeking a patent over the whole plant. The majority noted that "... a defendant infringes a patent when the defendant manufactures, seeks to use, or uses a patented part that is contained within something that is not patented, provided the patented part is significant or important."[282]

In this case, the majority found that the patent covered the cells and genes that compose the entire plant. Thus, infringement through use is possible where the patented invention is part of, or composes, a broader unpatented structure or process. This expansive rule was based on the principle, established in the patent and manufacturing context, of ensuring that a patentee cannot be deprived, even in part or indirectly, of his or her legal right to the full enjoyment of the monopoly. The application, by the majority, of this patent rule/principle to biological materials could be viewed as expanding patent protection from unlicensed use to a higher life form, i.e., a plant, when it is substantially composed of a patented invention, i.e., patented cells.[283]

Schmeiser had argued that the application of Monsanto's patent should be narrowly construed based on the majority decision in *Harvard Mouse* since the plants reproduce on their own, through the laws of nature. Propagation of the plant without a licence cannot therefore be a use by others because the plants are living things growing and reproducing without human intervention. The majority rejected this argument, noting that although other jurisdictions have adopted provisions to distinguish between unpatentable naturally occurring DNA sequences in the human body from patentable isolated DNA sequences, Parliament has not enacted a comparable statutory scheme to narrow the scope of patent construction.[284]

The majority stated that the restrictive approach adopted by the courts in the UK to exclude from patentability the naturally occurring form of DNA sequence in the body's cells was based on a regulatory scheme for which there was no equivalent in Canada.[285]

A final view of the Act's legislative scheme respecting infringement can be found in the partial dissenting opinion written by Justice Arbour. The dissent considered that the central issue was whether a patented product (the gene or the cell) extended patent protection to the unpatentable object into which it was incorporated, i.e., the canola plant.[286] It is interesting to note that three of the four person dissent in this case had formed part of the majority in *Harvard Mouse, supra*. It comes then as no surprise that the dissent advocated a restrictive approach to the scope of the patent for infringement purposes. The dissent narrowed the scope of Monsanto's patent by limiting its application solely to the laboratory.

In Justice Arbour's view, the patent over the chimeric gene and cell did not extend patent protection to the unpatentable plant which contained them.[287] The dissent considered that a patent would be invalid if the claim encompassed subject matter that was not patentable, in this case, a whole plant.[288] Monsanto's claims were found to be valid because they fell short of claiming patent protection over the whole plant, i.e., a higher life form incapable of patent protection.[289] The difficulty being that the plant can propagate without human intervention.

---

[280] *Ibid.* at para. 78.

[281] One could argue that *Monsanto*'s majority decision, by applying patent principles developed in the manufacturing context, extended patent protection from unlicensed use to a higher life form, i.e., an unpatented plant substantially composed of genetically altered patented cells.

[282] *Monsanto, supra* note 275, at para. 42.

[283] Three of the five member majority in *Monsanto, supra*, formed the dissent in *Harvard Mouse, supra*. In that case, the dissent disapproved of the PO's distinction between lower and higher life forms for the purposes of patentability. It advocated following the approach to patentability set out in the *Patent Act*. One might argue that the majority in *Monsanto* by extending patent protection to an entire plant is in fact signalling an end to the PO's distinction between higher and lower life forms.

[284] *Monsanto, supra* note 275, at para. 89.

[285] *Ibid.* at para. 89.

[286] *Ibid.* at para. 156.

[287] *Ibid.* at paras. 138 and 139.

The dissent considered that the patent claim over the plant cell ceased to apply once the cell containing the chimeric gene was placed in growth medium to begin regeneration in the laboratory.[290] Arbour J. acknowledged the difficulties encountered in trying to fit self-replicating biological materials within the confines of the *Patent Act* and considered that they warranted adopting a novel approach.[291] The dissent restricted the scope of the patent, for infringement purposes, by holding that it was valid only for the genetically modified chimeric genes and cells in the laboratory, prior to regeneration.[292]

The dissent concluded that Mr. Schmeiser had not infringed Monsanto's patent by saving, planting, or selling seed from the plant, since the patent did not extend to the plant itself.[293] Despite this restriction, Justice Arbour noted that the patentee would still control the use of the seed and could prohibit the saving of seeds from the plants through the licensing powers granted to them under the Act.[294]

Reports to Government

THE STANDING COMMITTEE ON HEALTH

In 2001, the House of Commons Standing Committee on Health, while reviewing the proposed *Assisted Human Reproduction Bill*, recommended in its report back to Parliament that: "The *Patent Act* be amended to prohibit patenting of humans as well as any human materials."[295] This recommendation was not adopted by Parliament.

THE CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

The Canadian Biotechnology Advisory Committee (the "CBAC") is an arms-length advisory group to the federal government. It is composed of scientists, academics, physicians, ethicists, and stakeholders. The mandate of the CBAC is to provide advice to the government on policy issues associated with the ethical, legal, social, regulatory, economic, scientific, environmental and health aspects of biotechnology.

In 2002, the CBAC released its report, entitled *Patenting of Higher Life Forms and Related Issues*.[296] The key issue addressed by the *Report* was whether Canada should permit the patenting of plants, seeds, and animals. It also examined the patenting of biological material generally.[297] The *Report* provided the federal government with thirteen recommendations. In arriving at its recommendations, the CBAC consulted with key non-governmental organizations, scientists and industry, as well as with the public through roundtable discussions held across the country in the spring of 2001 and through written input.[298]

The *Report* observed that in Canada there could be existing legal limits on a patentee's ability to exploit their invention, especially where that invention may pose risks to human or animal health or to the environment. Some of these legal limits are found in competition law, criminal law, the *Assisted Human Reproduction Bill* and in regulations governing product safety.[299] The position of the PO is that patents will not be granted for "higher life forms," which it describes as "multi-cellular differentiated organisms (plants, seeds and animals)."[300] This position is primarily what led to the challenge in *Harvard Mouse, supra*.

The *Report* suggested that questions of the patentability of higher life forms, such as the human body, should be dealt with by Parliament. In the CBAC's view, a patent on the human body would indicate a lack of appropriate respect for the subject-matter of the patent: it would engage the universal principle of basic human dignity. The *Report* emphasized one aspect of the principle of human dignity human beings are not commodities. It suggested that even if the granting of a patent on a human being was not a violation of human rights, the patentee's "exclusive right to make, use or sell an invented human would almost certainly violate the *Canadian Charter of Rights and Freedoms* and the *Canadian Human Rights Act*."[301]

---

[288] *Ibid.* at para. 138.
[289] *Ibid.*
[290] *Ibid.* at para. 130.
[291] *Ibid.* at para. 154.
[292] *Ibid.* at paras. 138 and 139.
[293] *Ibid.* at para. 162.
[294] *Ibid.* at para. 163.
[295] House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (2001), recommendation 34.
[296] CBAC, *supra* note 296.
[297] *Ibid.* at 2.
[298] *Ibid.* at 6.
[299] *Ibid.* at 7.
[300] *Ibid.* at 10.

With respect to the rights of the inventor to patent protection, the Report noted that this position ignores the real purpose of patent rights. Patent rights are best viewed as tools to achieve public good. The CBAC quoted Mr. Justice Jackson of the U.S. Supreme Court who in 1945 stated:

> The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances of knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure.[302]

If Canada decided to issue patents over higher life forms, the *Report* recommended that Canada's *Patent Act* be amended to prohibit the patenting of human bodies at all stages of development. This exemption would, however, only apply to patents claimed over the whole human body. The *Report* was careful to point out that such an exemption would still permit the granting of patents for sperm, ova, organs, human genes, cell lines and stem cells, since it is unlikely that such a patent would grant the patentee complete control over a human body containing that sequence or cell. However, it cautioned that this issue has never been addressed under the law.[303]

The *Report* recommended that higher life forms, i.e., plants, seeds and non-human animals, that meet the patentability criterion of new, useful and non-obvious be recognized as patentable.[304] However, this recommendation must be read together with the other recommendations in the *Report*, since they place limitations on patents for biological inventions, including protections for farmer's privilege, innocent bystanders, research and experimental use exceptions. The CBAC's rationale for imposing such limits was the unique reproductive nature of biological inventions and the fact that they can contain personal information. An unrestricted patent in a higher life form would grant to the patentee rights that could inhibit other useful activities, such as other research.[305]

The *Report* discussed the social and ethical considerations that arise when researchers and clinicians obtain biological materials from individuals. It recommended that the federal and provincial governments in Canada develop policies and practices that encourage the sharing of benefits reaped from research involving genetic material. The *Report* stated:

> ... we recommend that... the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who provided the material. All bodies (public, private and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed.[306]

In addition, the *Report* recommended that the PO issue guidelines on the patentability of biological materials.[307] A few of the CBAC's recommendations were implemented by the government, but none of the major recommendations discussed above have been implemented to date.[308]

In 2004, the CBAC issued an advisory memorandum to the federal government entitled "Rationalizing Patent Law in the Age of Biotechnology."[309] One of the stated purposes of the memorandum was to alert the government to issues of immediate importance and to provide recommendations to assist decision-makers in developing an effective course of action. The CBAC recommended:

---

[301] *Ibid.* at 13.

[302] *Sinclair & Carroll Co., Inc., v. Interchemical Corporation* 325 US 327 (1945) at 330-31 in Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (June 2002) at 12, Online: http//cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html. Accessed June 2004.

[303] *CBAC, supra* note 296, at 12.

[304] *Ibid.* at 16.

[305] *Ibid.* at 16.

[306] *Ibid.* at 23.

[307] *Ibid.* at 26.

[308] CIPO's Annual Report includes service standard and performance information (CBAC recommendation 11) while the PO Manual of Patent Office Practice is being updated in an on-going manner, as per CBAC recommendation 10.

[309] Canadian Biotechnology Advisory Committee, "Rationalizing Patent Law in the Age of Biotechnology" (Ottawa: CBAC, 2004). Online: http://www.cbac-cccb.ca

> The Federal Government should move quickly to review the *Patent Act* in light of the combined effects of the decisions of the Supreme Court of Canada on the patentability of the "Harvard mouse" and on the extent of the rights of a patent-holder of a modified cell in the recently-decided *Monsanto Canada Inc. v. Schmeiser* case.

The CBAC memorandum restated the same twelve recommendations found in the CBAC's 2002 report.

The Provinces

In 2002, the province of Ontario released its report entitled *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*.[310] The Ontario Report was endorsed by all the provincial and territorial premiers at their meeting in January 2002. It referenced the Standing Committee's recommendation to amend the *Patent Act*, but did not endorse it.[311] The Report recommended instead a comprehensive review of the Act and put forward a number of suggested amendments, including the introduction of an opposition period, additional infringement protection for healthcare providers, tightening utility requirements and restricting broad-based patents.[312] It noted that genetic materials are unique and can have multiple research uses. It suggested that granting patents over "concepts" or general, non-specific utilities in the area of genetic materials could be problematic since it can eventually impede research and development. The Ontario Report recommended tightening the scope of patents granted for genetic material by requiring that specific uses of sub-gene and stem cell patents be identified in the application and patent grant.[313]

It also recommended the addition of a provision to the Act, similar to an *ordre public* and morality provision, to limit patents on processes or procedures that are deemed contrary to Canadian morality or ethics. In addition, it recommended the addition to the *Patent Act* of an exclusion from patentability medical diagnosis using genetic materials.[314] The Report also recommended replacing the current 'methods of medical treatment' exclusion from patentability, created by the common law, with a provision stating that a patentee cannot bring an action for infringement against a medical practitioner for providing medical services, including both treatment and diagnosis, to patients.[315] It noted that adopting this approach, similar to that provided by a recent amendment to the U.S. *Patent Act*, would protect medical practitioners while still allowing the full patenting of genetic testing technologies.[316]

6.4.4 Academic Literature and Commentary

There is scant literature on the topic of human rights and patents over human bodily materials and the literature that does exist is mostly from the U.S.

Cyril R. Vidergar explores issues arising from the patenting of human materials in an article entitled, *Biomedical Patenting: Permitted, But Permissible?*[317] Vidergar is concerned that the lack of provisions in the U.S. *Patent Act* exempting human or human-derived materials from patentability may eventually cause Congress to legislate to ameliorate any potential threats to human dignity and autonomy.[318] He views bio-piracy (the taking of genetic material without a subject's knowledge) as impacting on constitutionally guaranteed rights under the 13th and 14th amendments, since it results in non-consensual commodification. He concludes that persons residing outside the U.S. are similarly protected from biological commodification under international laws and human rights treaties, such as the U.N. *Convention on Biological Diversity*, to which the U.S. is a signatory.[319] Vidergar notes, however, that despite these treaties and laws, the U.S. patent regime protects property right's claims to human materials derived without consent outside U.S. jurisdiction. He is concerned that there is no forum that would allow for the redress of what he terms "these potential violations of human autonomy."[320]

---

[310] Charting New Territory, *supra* note 26.
[311] *Ibid.* at iii and 31.
[312] *Ibid.* at iii.
[313] *Ibid.* at xi.
[314] *Ibid.* at xii.
[315] *Ibid.* at 51.
[316] *Ibid.* at 51.
[317] Vidergar, *supra* note 184.
[318] *Ibid.* at 266.
[319] *Ibid.* at 268-69.

He is also concerned with the effect biomedical patents may have on healthcare. For example, the inventor of a cell line that contains a particular gene may prevent others from similarly isolating an expression of that gene. Patentees may also charge exorbitant licensing fees for the use of their biomedical inventions, thus limiting the patients who can access a patented treatment or diagnostic to only those with a certain income level.[321]

Stacey Kincaid writing in *Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research,*[322] notes that in the U.S. a patent has been granted (Patent 6,200,806) to the University of Wisconsin's Wisconsin Alumni Research Foundation (the "WARF") over a method of isolating embryonic stem cells, as well as the stem cells themselves. She notes that this patent is the only one of its type in the world. The WARF has also applied for patents in Europe.[323] The isolated and patented stem cells have subsequently been developed into six distinct types, including: blood, liver, muscle, nerve, bone and pancreas cells.[324]

Kincaid refers to concerns with stem cell patents as essentially "ethical" and concludes that they arise because of the moral or special nature of the human embryo from which they were derived. She notes that some critics oppose the granting of these patents because they are patents over "life." She concludes, however, that these objections are largely "political in nature."[325]

R. Stephen Crespi provides a critique of the UK Nuffield Council Report (discussed earlier), in *Patenting and Ethics: A Dubious Connection.*[326] He notes that the Council believes that gene patents should be considered differently from other patents because of the issue of "ownership."[327]

In Crespi's view, the Council's Report erroneously equates a gene patent with gene ownership. He notes that a researcher who invented novel biological material would own it, regardless of whether he held a patent over it or not. Patent rights are different than ordinary property rights. A patent gives the patentee a right to exclude others from making, selling or using his or her invention for a time period fixed by law. In a legal action for patent infringement, the patentee does not assert that he or she owns the defendant's material, unlike a case of theft. If the defendant is found to have infringed the patent, he or she would most likely be required to pay damages to the patentee by, for example, an accounting of profits. This penalty for patent infringement is not in any way related to ownership of the infringing material."[328]

In the context of genes, Crespi notes that a person with a patent over DNA "owns" only the right to petition the court to stop other's unauthorized use of the isolated form of the claimed DNA.[329]

Crespi also discusses the Nuffield Report's assertion that "genes are essentially just information" and thus "the issue of patenting them [is] very different from that involved in the isolation of other chemical compounds."[330] In Crespi's view, this categorization of DNA would not stand up to legal analysis. He makes reference to the American case of *Amgen v. Chugai*[331] for the "classic statement" from the Court that "a gene is a chemical compound, albeit a complex one."[332]

There is no shortage of academic commentary highlighting moral and ethical concerns with the practice of patenting human genes. Some commentators start from the position that the human genome is the "common heritage of humanity."[333] This position is supported by the UNESCO *Declaration on the Human Genome and Human Rights*. Patents on human gene sequences are criticized because they are thought to grant exclusive rights over this common heritage to a limited number of entities.[334]

---

[320] *Ibid.* at 269.

[321] *Ibid.* at 269-70.

[322] Stacey Kincaid, *supra* note 184.

[323] *Ibid.* at 572-73.

[324] *Ibid.* at 573.

[325] *Ibid.* at 578.

[326] Crespi, *supra* note 183.

[327] *Ibid.* at 72.

[328] *Ibid.*

[329] *Ibid.*

[330] *Ibid.* at 75.

[331] *Amgen v. Chugai* (1989, 1991), 13 *US Patent Quarterly* 2d 1737 to 1797 and 18 *USPQ* 2d 1017 to 1031.

[332] Crespi, *supra* note 183, at 75.

[333] For a full discussion see B. M. Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey" (1999) 22 Nature Genetics 23.

[334] *ALRC, supra* note 4.

Other commentators are concerned that allowing patents on human genes will engender a lack of respect for human dignity. Patents, by bringing the human body and its parts to the market, lead to the commodification and objectification of the human body. Commodification and objectification have been described as:

> Commodification refers to the association of something or some practice with attitudes that ordinarily accompany a certain subset of commercial transactions. Objectification similarly refers to the act of treating someone, or something, as a commodity, but what is disturbing is not so much the exchange of money as it is the notion that a subject, a moral agent with autonomy and dignity is being treated as if it can be used as an instrument for the needs or desires of others without giving rise to ethical objections.[335]

The central concern being that the patenting of human biological materials, along with the associated transformation of these into routine objects of commerce, leads to a change in people's attitudes toward life and living organisms.[336]

There are some commentators who argue from a property perspective. For them, genes can be conceptually divided into two distinct entities: the DNA sequences themselves, and the genetic information they contain. The legal status of these two entities has not yet been settled in law. It is thought that the characterization of genes as either property, human beings, or some other legally recognized entity, will have enormous implications.[337] "These include symbolic and psychological implications that go to the very root of how human beings view themselves."[338] If genetic material is characterized as part of or as an extension of the human being from which it originated, then the law pertaining to persons could be held to regulate and protect the material. On the other hand, if the genetic material is characterized as property, then the law of property would most likely be found to regulate and protect it.[339]

It has been argued that patents over genes are incompatible with respect for an individual's self-determination (the right to make choices about how to live) because they grant ownership rights over parts of human beings.[340] Furthermore, self-determination is fundamentally linked to self-ownership (the right to choose how one's body is used) and thus granting a patent over genetic material is likened to allowing parts of people to be owned by others.[341] This argument has been criticized for confusing intangible intellectual property rights, in the form of patents, and physical property rights.[342]

6.4.5 Discussion

Under the *Patent Act*, the Commissioner must grant a patent if the "invention" meets the criterion of newness, non-obviousness and usefulness. In *Harvard Mouse, supra*, the five person majority upheld the PO's distinction between higher and lower life forms for the purposes of patentability, despite the fact that no such distinction exists in the Act.[343]

The dissent rejected the distinction and would have allowed the patent over the oncomouse.

A more recent case suggests that the members of the Supreme Court remain divided in their approach to questions of patentability and infringement with respect to biological materials. The majority in *Monsanto, supra*, held that the patent only applied to the chimeric gene and the plant cells into which the gene was inserted. However, since the gene and cells were in every part of the plant, any uses made of that plant would infringe the patent. As a result of the decision, the entire plant (a higher life form) is effectively protected from unlicensed use by the patent over its composite cells and genes. The dissent would have restricted the patent solely to uses in the laboratory since the plant, a higher life form, is capable of propagating on its own.

---

[335] T. Schrecker & a. Wellington, "Patenting of Biotechnological Innovations Concerning Animals and Human Beings" at 31.

[336] *Ibid.* at 33.

[337] M. Litman & G. Robertson, *supra* note 96, at 51.

[338] *Ibid.*

[339] *Ibid.* at 51-52.

[340] Resnik, *supra* note 40, at 155-159 (quoted in *ALRC, supra* note 4, at 52).

[341] *ALRC, supra* note 4 at 53-54. The authors also note at page 54 that this argument has been criticized.

[342] *Ibid.*

[343] One can argue, however, that the line between higher and lower life forms can be seen to have evolved in the case law. Beginning in *Abitibi, supra*, the Patent Appeal Board espoused that all new life forms produced en masse as chemical compounds and in such large numbers that "any measurable quantity will possess uniform properties and characteristics" would be patentable. The Board expressed doubts that an inventor of a higher life form could reproduce it at will and in a consistent manner. However, if he or she could, then it might be patentable. In *Pioneer Hi-Bred, supra*, the Court rejected a patent application for a new variety of soybean plant on the basis that the inventor had not altered the plant's reproductive process, it still followed the laws of nature, and thus the process could not be patented. Finally, in *Harvard Mouse, supra*, the Court majority opined that a patent over a higher life form would represent a significant increase in the scope of patent rights. Not only would the patent rights apply to the patented invention but also to its progeny since higher life forms reproduce on their own without human intervention. The scope of patent rights would not be consistent with rights granted in other fields.

The Courts decision in *Monsanto, supra,* arguably means that Harvard's oncomouse, which is substantially composed of patented genetically altered genes, would also be protected from unlicensed use. As a result of *Monsanto* and *Harvard College,* higher life forms, although not patentable subject matter, would be the subject of patent protection from the unlicensed use of the plant or oncomouse.

If in the future, the Canadian courts reversed and adopted a more expansive approach to the scope of patentability, and rejected the distinction between higher and lower life forms, concerns with the inability to exempt certain biological materials from patentability under the *Patent Act* might force the issue before Parliament.

6.4.5.1 Could the grant of a patent over excised bodily materials raise any human rights issues?

Advances in biotechnology in the area of science and medicine will continue to push the existing boundaries of patentability and will most likely result in patented inventions using human materials in ways not yet contemplated. It is possible that some of these patented inventions will raise human rights issues, especially if the patent limits a person's autonomy and self-determination.

It is possible to grant a patent for the process of isolating and characterizing a human cell, such as a liver cell. No one else, including the donor, could use or patent that particular cell, arguably even for a different use, without first obtaining a licence from the patentee. Could the grant of such a patent raise any human rights issues?

The following hypothetical is used to illustrate some of the issues that may arise. The hypothetical may be considered by some as mere "science fiction," but in fact much of the science described is within the realm of possibility today.

> Jane Doe fully and freely consents to donate her liver cells for research purposes. The researcher successfully isolates and uses Jane's cells to invent a cell line with the potential to develop cures for individuals with cirrhosis of the liver. The researcher applies for and is granted a patent over the process (isolation, characterization and expression) and over the resulting cell line. Five years later, Jane Doe develops serious liver disease. Her physician would like to isolate Jane's liver cells and have a personalized cure developed for Jane.

Her physician requests a licence from the patentee in order to use the patented process to successfully isolate Jane's cells, but the patentee refuses to grant the requisite licence.[344] If her physician proceeds, without a licence, the patentee has a right under the *Patent Act* to bring an action in court against the physician and possibly against Jane for patent infringement. In addition, the patentee may seek an injunction restraining Jane and her physician from using the patented process (sections 54(1) and 57(1)(a) of the *Patent Act*). Jane and her physician believe that the inability to use the patented process to successfully isolate her cells to possibly create a life-saving therapy engages Jane's human rights.

***Relief under the* Patent Act**

Under section 19, a government may seek authorization from the Patent Commissioner to use the patented invention, which includes a patented process. However, the authorization to use obtained by the government under section 19 is not transferable. Moreover, the government must establish that it made attempts in the past, over a reasonable period of time, to obtain authority to use the patented invention from the patentee, unless it establishes that the use is required because of national emergency or extreme urgency or where the use required is a public non-commercial use (s. 19.1). It is possible that the government could make a good argument that Jane's case is one of "extreme urgency" and thus succeed in obtaining a licence from the patentee.

---

[344] Under section 19(1) of the *Patent Act*, the Patent Commissioner on application by the federal or a provincial government may authorize the use of a patented invention by that government. The Commissioner would have to be satisfied that the applicant (government) made efforts to obtain authority from the patentee to use the invention (s. 19.1), unless it is a case of national emergency or extreme urgency or is a public non-commercial use (s. 19.1(2)). The commissioner's decision under these sections may be appealed to the Federal Court (s. 19.2). Section 65 of the Act sets out a similar provision, however, three years must have passed since the grant of the patent before it can be relied on. After the requisite three years, the Attorney General of Canada or any person interested may apply to the Commissioner alleging that the patentee has abused his or her exclusive rights granted under the patent and seek relief under the Act.

In addition, under section 65 of the Act, the Attorney General of Canada or any person may apply to the Commissioner alleging that the patentee has abused his or her exclusive rights and ask for relief under the Act, but only after the expiration of three years from the date on which the patent was issued. This provision presents a less attractive option for Jane and her physician because they must wait the requisite three years to apply.

Finally, under the research exemption, a researcher could be commissioned by Jane to study the patented process without first obtaining a licence from the patentee. The researcher would hopefully be able to design his or her own method of successfully isolating the cells and creating a cure for Jane. The research exemption presents another option, but once again it requires time to study the patented process and hopefully to succeed in inventing an equally successful one.

A Human Rights Challenge

Jane believes that the ability of the patentee to prevent her from accessing a possible cure engages her right to health, liberty and security of the person. Jane could look to international human rights instruments for relevant human rights standards.

With respect to a right to health, the most relevant human rights instrument is the ICESCR, specifically articles 12 and 15. Article 12 provides a fundamental right to the enjoyment of the highest attainable standard of health. It contains the most important recognition of the right to health in an international convention.[345] The U.N. Committee's Commentary on article 12 suggests that the right to health contains both freedoms and entitlements. The freedoms include the right to control one's health and body, and the right to be free from interference.[346] These articles and any relevant commentary could be put before the Canadian courts to inform their interpretation of the *Charter* and of the *Patent Act*.

In addition, the ICESCR provides a right to benefit from scientific progress in article 15, paragraph (1)(b). Committee Commentary on this article suggests that the fundamental human rights of the person should prevail over the rights of the patentee set out in article 15, paragraph (1)(c). As noted earlier, there is scant academic literature or commentary on this provision. The Committee of the ICESCR is currently preparing a draft Commentary to assist States Parties in their interpretation of the article.

The Committee of the ICESCR has made it clear in the past that there is a distinction to be made between fundamental human rights and intellectual property rights, which are the product of instrumental and temporary regimes created by the State. One could argue that article 15 imposes an obligation on States to adopt an approach to intellectual property rights which ensures the primacy of human well-being. Fundamental human rights which are timeless should trump intellectual property rights, which are generally of a temporary nature and which can be revoked, licensed or assigned to someone else.

An argument could be made that an exception to infringement should be recognized to allow Jane and her physician to use the patented process to extract and isolate her liver cells, without a licence, on the basis of medical necessity. The patent is preventing Jane from accessing a possible medical cure that would possibly enable her to enjoy the highest attainable standard of health: she is unable to submit to a personalized cure that could return her to optimum health.

6.4.5.2 Could the grant of a patent over a process for isolating excised human materials engage any human rights under the *Charter*?

***The* Charter**

The *Charter* provides Canadians with certain guaranteed rights and freedoms. It applies to all government actions such that legislation and regulations must be *Charter* compliant. This includes all levels of government in

---

[345] Virginia A. Leary, "Implications of a Right to Health" in *Human Rights in the Twenty-First Century: A Global Challenge*, edited by Kathleen E. Mahoney and Paul Mahoney (Dordrecht, The Netherlands: Martinus Nijhoff Publishers, 1993) at 488.

[346] U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000), Dstr. General E/C.12/2000/4 11 August 2000.

Canada: federal and provincial (including municipal), and would most likely include the actions of a government or Crown agent, depending on the circumstances.

In those instances where the government action has been found to infringe a *Charter*-protected right or freedom, the government must establish that the infringement is prescribed by law and must justify the infringement under section 1 of the *Charter*, which states:

> s. 1 The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Section 1 allows the government to justify an infringement of individual rights as being a reasonable limit in a free and democratic society on the basis of broader societal concerns or objectives, where the infringement is prescribed by law.

The most relevant human rights interests raised by the hypothetical are those provided in section 7 of the *Charter*. It states as follows:

> s. 7. Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

Under section 7, the government may deprive a person of his or her right to life, liberty and security of the person, but only where the deprivation is in accordance with the principles of fundamental justice. The principles of fundamental justice operate to qualify the rights in section 7. The Supreme Court of Canada has held that the principles of fundamental justice are found in the tenets of the legal system and are legal principles about which there is a high degree of societal consensus.

If the courts find that the government deprivation is not in accordance with the principles of fundamental justice, the inquiry may end there without the court going further and asking whether the government could justify the deprivation under section 1 of the *Charter*. The courts may consider that the infringement of section 7 is so egregious that it could not be justified under section 1. On the other hand, the courts may look to the government for arguments justifying its limit on a guaranteed human right. The onus is on the government under the section 1 inquiry to establish that the deprivation or limit is prescribed by law and is justified in a free and democratic society.

The two inquiries are based on different considerations. The Supreme Court has noted:

> ... despite certain similarities between the balancing of interests in ss. 7 and 1, there are important differences, Firstly, the issue under s. 7 is the delineation of the boundaries of the rights and principles in question whereas under s. 1 the question is whether an infringement may be justified... Secondly, it was affirmed that under s. 7 it is the claimant who bears the onus of proof throughout. It is only if an infringement of s. 7 is established that the onus switches to the Crown to justify the infringement under s. 1. Thirdly, the range of interests to be taken into account under s. 1 is much broader than those relevant to s. 7... [b]ecause of these differences, the nature of the issues and interests to be balanced is not the same under the two sections.[347]

In the past, section 7 was viewed as applying solely in the criminal and quasi-criminal law context. The Supreme Court of Canada, however, has held that the rights under section 7 are not confined solely to these areas of the law.

In *B. (R.) v. Children's Aid Society of Metropolitan Toronto*,[348] the Supreme Court of Canada held that the liberty interests of the parents were engaged under section 7 of the *Charter* when the state intervened under statute to grant wardship of a child to the Children's Aid Society in order that the child could receive a blood transfusion.

---

[347] *R. v. Malmo-Levine; R. v. Caine*, [2003] 3 S.C.R. 571, at para. 97.

[348] *B. (R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315 [hereinafter referred to as *B(R)*]

Lamer C.J. stated in *New Brunswick (Minister of Health and Community Services) v. G.(J.)*[349] that:

> … s. 7 is not limited solely to purely criminal or penal matters. There are other ways in which the government, in the course of the administration of justice, can deprive a person of their s. 7 rights to liberty and security of the person, i.e., civil committal to a mental institution.[350]

In *Blencoe v. British Columbia (Human Rights Commission)*,[351] the Supreme Court building on its decisions in *B(R)* and *G(J)*, stated that "… there is no longer any doubt that s. 7 of the *Charter* is not confined to the penal context."[352] It may be engaged in non-criminal law cases where the state action directly engages the justice system and its administration.[353]

In *Chaoulli v. Quebec (A.G.)*,[354] three members of the Supreme Court held that s. 7 was engaged despite the fact that the case considers issues arising outside both the criminal justice system and the administration of justice.[355] It remains to be seen whether this broadening of the application of s. 7 outside the criminal and administration of justice context by three members of the Court continues or will be restricted to circumstances similar to that of *Chaoulli*.

With respect to the hypothetical, the first question is whether there is a government action that could deprive Jane of her section 7 right to life, liberty and/or security of the person.

An argument could be made that there is government action. Patents are granted by the Commissioner of Patents who is appointed by the Governor in Council and who exercises the delegated powers and perform the duties conferred on him or her by the Act. The Commissioner acts in reliance to a statutory power, i.e., the *Patent Act*, and thus the *Charter* would most likely apply to the Commissioner's actions, including his or her decisions regarding patents. Peter W. Hogg notes that the *Charter* will apply to:

> … actions taken by the cabinet, by individual ministers and by public servants within the departments of government,… including Crown corporations and public agencies that are outside the formal departmental structure, but which, by virtue of a substantial degree of ministerial control, are deemed to be "agents" of the Crown.[356]

One could argue that the grant of a patent by the Commissioner under the *Patent Act* is an action that is subject to the *Charter*. However, the act of issuing a patent to an inventor for a process to isolate human cells is unlikely to engage any *Charter* rights. The patent only applies to the process of successfully isolating Jane's cells.

Arguably, problems arise for Jane only in those instances where the patentee refuses to grant a licence to allow her physician to use the patented process to isolate her liver cells. Is the patentee's decision not to issue a licence to Jane's physician subject to *Charter* scrutiny?

One might argue that the patentee's decisions with respect to licensing are not controlled by government.[357] On the other hand, could an argument be made that the patentee's licensing decisions are government since they are made in reliance on a statutory power and thus subject to the *Charter*?

The grant of a patent under the Act provides the patentee with exclusive rights to use, make or sell the invention. In addition, the Act provides that if the invention is made, used or sold without the permission of the patentee (in the form of a licence-to-use), the patentee may apply to court for damages relating to patent infringement. Although the statute provides certain rights to the patentee and a remedy when those rights are infringed, any licensing decisions on the part of the patentee are not made in reliance on a statutory power. The patentee's licensing decisions are not for the most part subject to government control (only when the patentee has abused his or her patent rights may s. 65 of the Act be engaged). The patentee's licensing decisions are *not made* on the basis of a delegated statutory authority.

---

[349] *New Brunswick (Minister of Health and Community Services) v. G.(J.)*, [1999] 3 S.C.R. 46 [hereinafter referred to as *G(J)*].

[350] *Ibid.* at para. 65

[351] *Blencoe*, *supra* note 87.

[352] *Ibid.* at para. 45.

[353] *Ibid.* at para. 46.

[354] *Chaoulli v. Quebec (A.G.)*, [2005] SCC 35 [hereinafter referred to as *Chaoulli*].

[355] *Ibid.* at para. 153.

[356] Peter W. Hogg, *Constitutional Law of Canada*, Loose-leaf Edition (Scarborough: Thomson Carswell, 1997) at 34.2(e).

[357] The *Patent Act* provides for government intervention in a patentee's licensing decisions but only where the government can establish that the patentee has abused the exclusive rights granted under the patent and only three years after the grant of patent (sections 65 and 66 of the *Patent Act*).

In the hypothetical, Jane's inability to successfully isolate her liver cells results directly from the patentee's refusal to issue a license to Jane and her physician. The patentee is arguably a private entity whose licensing decisions are for the most part free of government control. In conclusion, Jane could likely not challenge either the government or the patentee on the basis of a deprivation of a *Charter* right.

The analysis and conclusion, however, would be different if the patent was held by a government department. In that case, the refusal to grant a licence could be characterized as a government action, which would be subject to *Charter* scrutiny.

Under the hypothetical, there may be one successful argument that Jane could make regarding the *Charter*. Although the decision by the private patentee respecting the granting of licences to use a patented invention would not likely be considered government action, a court ordered injunction, one of the remedies available in a dispute between private parties under the *Patent Act*, may be found by the courts to be government action subject to *Charter* scrutiny.

Peter W. Hogg suggests that, based on Supreme Court jurisprudence, if the court order was issued to resolve a matter between two private parties, and if it was based solely on the common law, it would *not* be considered government action and thus the *Charter* would not apply. However, if the court order was issued in a purely private dispute that was governed by statute law, then the *Charter would* apply to the order.[358]

If Jane and/or her physician decided to proceed and infringe the patent by undertaking an unlicensed extraction and isolation of her cells, the patentee could exercise his or her statutory rights in court, and seek damages and an injunction. The court-ordered injunction is one remedy available under, and governed by, the *Patent Act* for the resolution of private disputes. The injunction could be considered government action subject to *Charter* scrutiny.

Jane could argue that the courts must, prior to issuing an injunction, first subject it to *Charter* scrutiny. She could argue that the injunction would prevent her and her physician from devising a possibly lifesaving medical therapy and thus would engage her *Charter* right to liberty and to security of the person.

In *R. v. Morgentaler*,[359] Chief Justice Dickson, writing for himself and Justice Lamer, stated:

> ... that state interference with bodily integrity and serious state-imposed psychological stress, at least in the criminal law context, constitute a breach of security of the person.[360]

Justice Wilson, writing one of the majority opinions and speaking for herself, agreed with the Chief Justice and with Justice Beetz, noting that "... the right to security of the person under s. 7 of the *Charter* protects both the physical and psychological integrity of the individual."[361] Beetz, J., writing for himself and Justice Estey, was of the view that "... the constitutional right to 'security of the person' must include some protection from state interference when a person's life or health is in danger... [but] section 7 cannot be invoked simply because a person's life or health is in danger... [t]here must be state intervention for 'security of the person' in s. 7 to be violated."[362]

In *Rodriguez v. British Columbia (Attorney General)*,[363] Justice Sopinka, writing for the majority, noted that the right to security of the person "... can be seen to encompass a notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress."[364] Note, however, that both *Rodriguez* and *Morgentaler, supra* considered the right to security of the person in the criminal law context.

---

[358] Hogg, supra note 356 at 34.2(f). Peter Hogg distinguished the Supreme Court's decision in *Dolphin Delivery* (a dispute between private parties relying on the common law) from its decisions in both *R. v. Rahey* and *British Columbia Government Employees' Union v. British Columbia* (a purely private dispute governed by statute law).

[359] *R. v. Morgentaler*, [1988] 1 S.C.R. 30 [hereinafter referred to as *Morgentaler*].

[360] *Ibid.* at 56.

[361] *Ibid.* at 173.

[362] *Ibid.* at 90.

[363] *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519 [hereinafter referred to as *Rodriguez*].

In *R. v. Parker,*[365] the Ontario Court of Appeal was asked whether prohibitions under two federal statutes regarding the cultivation and possession of marihuana violated section 7 *Charter* rights to security of the person and to liberty.[366] The respondent, Parker, alleged that the prohibitions interfered with his health and therefore his security of the person and liberty interests.

The Court of Appeal noted that *Morgentaler, supra,* is the leading case where medical treatment and the criminal law intersect. In that case, state interference with bodily integrity and state-imposed psychological stress, at least in the criminal law context, constituted a breach of security of the person. This view of the right to security of the person is consistent with the view espoused in *Rodriguez, supra* and *G(J), supra.*[367]

The Court of Appeal relying on the Supreme Court's comments in *Morgentaler, supra* and *Rodriguez, supra* held that:

> … deprivation by means of a criminal sanction of access to medication reasonably required for the treatment of a medical condition that threatens the life or health constitutes a deprivation of security of the person… Depriving a patient of medication in such circumstances, through a criminal sanction, also constitutes a serious interference with both physical and psychological integrity.[368]

And later in the decision:

> … the constitutional right to security of the person must include some protection from state interference when a person's life or health is in danger… There must be state intervention for "security of the person" in s. 7 to be violated. If a rule of criminal law precludes a person from obtaining appropriate medical treatment when his or her life or health is in danger, then the state has intervened and this intervention constitutes a violation of that man's or woman's security of the person. *Security of the person must include a right of access to medical treatment for a condition representing a danger to life or health without fear of criminal sanction. If an Act of Parliament forces a person whose life or health is in danger to choose between, on the one hand, the commission of a crime to obtain effective and timely medical treatment and, on the other hand, inadequate treatment or no treatment at all, the right to security of the person has been violated.*[369] [emphasis added]

If Jane and her physician ignore the court-ordered injunction and choose to create the medical therapy, they risk being held in contempt of court, with the possibility of imprisonment and/or a fine. Jane's choice is between, on the one hand, potential loss of liberty in order to receive medical treatment and on the other hand, inadequate or no treatment at all. An argument could be made that Jane's right to security of the person would have been engaged.

In *G(J), supra,* Chief Justice Lamer, writing for the Supreme Court, stated:

> … the restrictions on liberty and security of the person that s. 7 is concerned with are those that occur as a result of an individual's interaction with the justice system and its administration. In other words, the subject matter of section 7 is the state's conduct in the course of enforcing and securing compliance with the law, where the state's conduct deprives an individual of his or her right to life, liberty, or security of the person ... however, s. 7 is not limited solely to purely criminal or penal matters. There are other ways in which the government, in the course of the

---

[364] *Ibid* at 587-88.

[365] *R. v. Parker* (July 31, 2000) [hereinafter referred to as *Parker*] Online: http://www.canlii.org/on/cas/onca/2000/2000onca359.html.

[366] At trial, the judge held that the prohibitions violated the respondent's *Charter* rights under s. 7 to life, liberty and security of the person and were contrary to the principles of fundamental justice. Instead of striking down the prohibition, the trial judge read in an exemption for persons cultivating or possessing marihuana for their personal medically approved use.

[367] *Parker, supra* note 365, at 18.

[368] *Ibid* at 20.

[369] *Ibid* at 22.

> administration of justice, can deprive a person of their s. 7 rights to liberty and security of the person, i.e., civil committal to a mental institution.[370]

It could be argued that although the hypothetical does not engage the criminal justice system, the injunction would be issued as a result of Jane's interaction with the justice system and its administration. Section 7 of the *Charter* would thus be engaged.

The courts might agree that Jane's section 7 *Charter* rights to liberty and to security of the person would be violated by a court-ordered injunction. The courts would then proceed to the next stage of inquiry under section 7 and determine whether the state deprivation would be in accordance with the principles of fundamental justice. This step requires the identification and definition of the relevant principles of fundamental justice by the complainant. At this point in time, it would be highly speculative to consider what such principles, if any, may be relevant.

If the courts determine that the deprivation was in accordance with the principles of fundamental justice, then it would be considered constitutional. If, on the other hand, the courts conclude that the deprivation was not in accordance with the principles of fundamental justice, a *Charter* deprivation would have been made out by the complainant. The courts may conclude that the state would be unable to justify the deprivation under section 1 of the *Charter*, or it might look to see whether the state has justified the deprivation as a reasonable limit prescribed by law in a free and democratic society.

The courts faced with such a compelling situation might create a common law exemption or defence to patent infringement similar to what has been proposed by legislators in the U.S. (an extension of the medical treatment defence). The courts might design the defence to allow licensed physicians and heath care facilities to use the unlicensed process when undertaking a medically necessary activity.

Although the hypothetical dealt with the patenting of a process, the same analysis would apply if the patented subject matter was an isolated human gene. It is important to note that this analysis is based on hypothetical facts. It is possible that with different facts before it, the courts would undertake a different analysis. In the case where the patentee was a government department, the dispute would no longer be between two private parties, but would directly implicate an action, the refusal to license, by government and would be subject to *Charter* scrutiny.

6.4.5.3 Could the grant of a patent over a genetic therapy that self-replicates within the human body engage any rights under the Charter?

The following hypothetical is provided to assist with the analysis and discussion:

> Jane Doe discovers, after genetic testing, that she carries the gene for a late-onset disease, Huntington's chorea. Researchers have recently developed a process for delivering an engineered gene to replace the Huntington's gene, via a retrovirus (a type of vector), in all of the body's cells, including her germ or sex cells. The researchers patent the healthy DNA sequence, but not the delivery process since it is a form of medical treatment and as such is not patentable. Once inside Jane Doe's body, the engineered gene knocks out and replaces the Huntington's gene in all her cells.
>
> Jane decides to have a child. She wonders however, whether the process of reproducing whereby she would pass the genetically engineered healthy gene to her offspring would violate the patent. The patentee claims that it would and that Jane would first require a licence from the patentee before she could reproduce. Would such a patent engage Jane's human rights?

As noted earlier, a patent grants to the patentee the right to exclude others from using, making or selling the invention. The nucleus in Jane's cells, including her ova or eggs contains the patented gene. It could be argued that, by reproducing, Jane has "used" or "made" the patented gene without first obtaining a licence from the patentee and thus she would have infringed the patent.

---

[370] *G.(J.) supra* note 349, at para. 65.

The same arguments and analysis would apply to this situation that applied with respect to the first hypothetical. Assuming the patentee is a private entity and not a government entity, it is unlikely that the *Charter* would be available to assist Jane.

If Jane proceeded to reproduce and her offspring inherited the genetically-altered gene, what would be the patentee's options? The patentee could seek a court ordered injunction prohibiting Jane and her offspring from reproducing without a licence. Jane would argue that the *Charter* is engaged because the court-ordered injunction would be a resolution to a private dispute that is governed by legislation (the *Patent Act*), and thus qualifies as a government action.[371]

It is highly unlikely that a court would issue such an injunction. First, it could be argued that under international human rights instruments, persons have a right to reproductive autonomy (see the arguments in Chapters 2 and 3). These human rights instruments would be introduced to assist the Canadian courts in their interpretation of the *Charter* and of the *Patent Act*.

In addition, as noted earlier, the jurisprudence under s. 7 of the *Charter* suggests that the right to liberty and security of the person include the right to reproductive autonomy. It is unlikely that the courts would issue an injunction preventing a person from reproducing. This would most likely be a case where fundamental human rights (Jane's right to reproduce) would trump intellectual property rights (the rights of the patentee).

6.5 Does the Patenting of a Human In Vitro Embryo Raise any Human Rights Issues?

*(Note: in this section the term "*in vitro *embryo" is used to describe the fertilized human egg from the moment of fertilization to the fœtal stage, which begins eight weeks post fertilization)*

6.5.1 International and Regional Instruments

International Human Rights Instruments

The ICCPR provides the following in article 8, paragraphs 1 and 2:

> *Article 8*
>
> 1. No one shall be held in slavery; slavery and the slave-trade in all their forms shall be prohibited.
>
> 2. No one shall be held in servitude.

Article 8, paragraphs (1) and (2), are considered to guarantee some of the most fundamental human rights: freedom from slavery and servitude.[372] Slavery occurs when one person owns another such that the former can totally exploit the latter with impunity.[373] Article 8, paragraph (1), prohibits slavery. Article 8, paragraph (2), prohibits servitude which is a broader concept than slavery. It includes other forms of egregious economic exploitation or dominance by one person over another, as well as slavery-like practices.[374]

The Human Rights Committee (the "HRC") has expressed concerns with the practice of "bonded labour" in India as a possible violation of article 8. Bonded labour is a practice where a debtor pledges either his or her personal services, or the services of someone they control (often a child), as security for the debt.[375] The HRC has expressed deep concerns with other activities, including the trafficking in women for the purposes of prostitution and child labour and prostitution, which violate article 8. State Parties are responsible for protecting all persons within their jurisdiction from article 8 abuses by private bodies, as well as by the State itself.[376] Canada, as a party to the ICCPR, is obliged to comply with its provisions. Although the provisions of the ICCPR could not form the basis of an action in a Canadian court, they could be cited to support a particular interpretation of the *Charter* or of domestic legislation, such as the *Patent Act*.

---

[371] Hogg, *supra* note 356, at 34.2(f).

[372] Sarah Joseph, Jenny Schultz, and Melissa Castan, *the International Covenant on Civil and Political Rights: Cases, Materials, and Commentary* (Oxford: Oxford University Press, 2000) at 198.

[373] *Ibid.* at 199.

[374] *Ibid.*

[375] *Ibid.*

[376] *Ibid.* at 199-200.

Trade Agreements

Canada is a member of the WTO and thus must comply with the provisions of the TRIPS Agreement. In the event of a dispute and non-compliance, Canada could face possible retaliation in the form of trade sanctions. Article 27, paragraph (2), allows members to exclude from patentability certain subject matters in order to protect *ordre public* or morality within their territory, as long as the exclusion is not made merely because the exploitation is prohibited by law. It states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

According to European law, the term "*ordre public*" encompasses the protection of public security and the physical integrity of individuals as part of society, as well as the environment.[377] The EPO Guidelines for Examination notes that *ordre public* is linked to "security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour."[378] The EPO also must examine the morality of the commercial exploitation of a particular invention. It must establish whether an invention would be so morally abhorrent that its patenting would be inconceivable to the public. The term "morality" encompasses all of the accepted norms which are deeply rooted in a particular culture.[379] It should be noted, however, that a marketing prohibition by a Member State cannot be used to justify its exclusion from patentability on the grounds of *ordre public* or morality. There must be a connection between the State law prohibiting marketability and *ordre public* or morality.[380]

There is of course no requirement for WTO Members to follow the European approach as set out above. Members have the flexibility to determine which situations are covered by the phrase *public ordre* and what constitutes morality in their particular community.[381]

Regional Instruments

Although Canada is not a member of the Council of Europe, it has observer status. The human rights instruments adopted by the Council are thus not binding on Canada. The instruments and how they have been interpreted may, however, be used by the courts to inform their interpretation of the *Charter*, as well as domestic legislation.

Article 18, paragraph (1), of the *Convention on Human Rights and Biomedicine*[382] provides that where research is permitted by law on an *in vitro* embryo, that law must ensure its protection. Article 18, paragraph (2), prohibits the creation of a human embryo solely for research purposes.

The European Parliament and the Council's *Directive*[383] provides in article 6, paragraph (2)(c), that the use of *in vitro* embryos for industrial or commercial purposes cannot be patented because their commercial exploitation would be contrary to *ordre public* or morality. In also provides in article 5, paragraph (1) that the human body at any stage of development and formation, including the sequence or partial sequence of a gene, does not constitute a patentable invention.

The Organization of American States (the"OAS") is a regional organization with membership from South and Central American, the Caribbean, the U.S. and Canada. It is a regional agency within the meaning of Article 52 of the U.N. *Charter*. In 1969 the OAS adopted the *American Convention on Human Rights* (the "*Convention*").[384] Canada is neither a signatory to nor has it ratified the *Convention*.

---

[377] United Nations Conference on Trade and Development (UNCTD) secretariat and the International Centre for Trade and Sustainable Development, Draft *TRIPS and Development: Resource Book* (Geneva, 2002) at 2.5.3 (page 40). Online: http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (accessed April 20, 2005).

[378] *Ibid.* at 2.5.3 (pages 40-41).

[379] *Ibid.* at 2.5.3 (page 41).

[380] *Ibid.* at 2.5.3. (page 39).

[381] *Ibid.* at 2.5.3 (page 40).

[382] *Convention, supra* note 131.

[383] *Directive, supra* note 138.

[384] *American Convention on Human Rights*, O.A.S. Treaty Series No. 36, 1144 U.N.T.S. 123, entered into force 18 July 1978.

Article 4, paragraph (1), of the *Convention* states:

> Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of life.

This article qualifies the protection of the unborn with the phrase "in general." The *Travaux Préparatoires* to the *Convention* notes that there was strong opposition by some members to a proposal to delete the phrase "in general." There was concern that the right to lawful abortion, which exists in some States, might be compromised. A majority of the Members States, however, were of the view that article 4 should protect the life of the unborn since they consider abortion a crime.[385]

6.5.2 The Law in Other Jurisdictions

The U.S.

The U.S. *Patent Act* does not provide an exhaustive list of subject matters that are not patentable. As long as the invention is a new or useful process, machine, manufacture or composition of matter, it may be patented. The U.S. Congress considers this list of subject matter to be quite broad and to include "anything under the sun that is made by man."[386] The courts have, however, excluded certain things from patentability, including the laws of nature and natural phenomena, including a mineral in the earth and a plant in the wild.[387]

In the report entitled *Reproduction and Responsibility: The Regulation of New Biotechnologies*,[388] the President's Council on Bioethics notes that there is no provision in the *Patent Act* that expressly provides for the consideration of morals in determining patentability. The Report notes that to date patents have been granted over modified human tissues and cell lines, as well as human DNA. It points out that the prospect of future patents over human gametes and embryos raises ethical concerns.[389] The Council notes that, for one thing, since the patent would create a quasi-property right in another, or in a part of another, a patent over a human embryo would be deeply troubling.[390] The Report recommends that Congress amend the patent laws to prohibit the patenting of human embryos and restrict the patenting of human sperm and ova.[391]

State law

There is at least one state, Louisiana, that assigns legal rights to the human *in vitro* embryo from the moment of conception. The Louisiana *Civil Code* protects the *in vitro* embryo and deems it to be a juridical person who can sue and be sued, until such time as it is transferred into a woman's womb.[392]

Case law

On February 6, 2005, a Cook County judge in the state of Illinois ruled, in a case involving a mistakenly discarded *in vitro* embryo, that the embryo was legally a "human being."[393] The couple were experiencing infertility and sought the assistance of a fertility clinic. After successful treatment, the couple believed that their *in vitro* embryo had been cryopresserved by the Center for future reproductive use. However, when the couple returned two years later to undergo further fertility treatments, with the *in vitro* embryo, they discovered that the Center had mistakenly discarded their embryo.[394]

The couple sued for damages claiming that the Center's disposal amounted to a case of wrongful death. The claim was rejected by two judges prior to the ruling by Judge Lawrence which found in favour of the couple. Judge Lawrence wrote:

> Philosophers and theologians may debate, but there is not doubt in the mind of the Illinois legislature when life begins. It begins at conception.[395]

---

[385] See chapter 2 footnote 246.

[386] Sheldon w. Halpern, et al., *supra* note 10, at 227.

[387] *Ibid.* at 227 (relying on *Chakrabarty, supra* and *Diehr, supra*).

[388] The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (Washington, D.C., March 2004) at 160. Online: http://www.bioethics.gov.

[389] *Ibid.*

[390] *Ibid.*

[391] *Ibid.* at 181 and 202.

[392] Louisiana *Civil Code* § 26 (1988).

[393] Patrick Rucker, "Judge says lost embryo a human, ruling clears way for couple's suit" *Chicago Tribune* (6 February 2005).

[394] *Ibid.*

[395] *Ibid.*

At the time of writing, the lawyer for the Center was still considering a response to the decision. A number of commentators were of the view that the judge had misrepresented state law and had relied on language from an invalidated state abortion law.[396]

The UK

The UK *Patent Act*[397] provides in section 1(3) the ability to exclude from patentability "... an invention, the commercial exploitation of which would be contrary to public policy or morality." The UK *Human Fertilisation and Embryology Act*[398] was recently amended to allow the creation of human *in vitro* embryos solely for research purposes.

The UK is obliged to follow the *Directive*. The UK PO recently issued a practice note confirming that it will not grant patents over processes for obtaining stem cells from human embryos since it believes that these processes are excluded from patentability by the *Directive's* prohibition of the uses of human embryos for industrial or commercial purposes.[399] Furthermore, the PO will not grant patents over human pluripotent cells because of their potential to develop into an entire human body.[400]

6.5.3 Canada

It is unclear whether the Commissioner of Patents would grant a patent over a human *in vitro* embryo at the single-cell stage of development. PO practice provides that higher life forms, i.e., seeds, plants and animals (multicellular organisms), are not patentable subject matter.

Both the dissent and majority opinion in *Harvard College, supra,* considered in *obiter* that a genetically modified fertilized mouse egg (a unicellular mouse embryo) would likely constitute patentable subject matter.[401] If faced with a patent application for a unicellular or pronuclear human *in vitro* embryo,[402] the Commissioner may consider the central issue to be whether a unicellular organism can be considered a "higher life form" for the purposes of the *Patent Act*.

The dissent in *Harvard College, supra,* and, to some extent, the majority in *Monsanto, supra,*[403] noted that that questions of patentability, patent infringement and, to some extent, scope are to be resolved by the application of established principles of patent law, not principles of morality or ethics, which are matters more properly left to Parliament. Although section 40 of the *Patent Act* requires the Commissioner to reject a patent application if he or she believes that it would contravene the law, there is no law in Canada prohibiting the patenting of a human *in vitro* embryo.

The majority in *Harvard College, supra,* also commented in *obiter* that it saw no reason for altering the line drawn by the PO between higher and lower life forms for the purposes of patentability.[404] Justice Bastarache stated:

> ... I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two.[405]

In Canada today, the common law has thus drawn the patentability line between higher and lower life forms. The question as to whether certain human biological materials will be patentable depends in part on the Patent Commissioner's determination as to whether they are a higher or a lower life form. For example, a pronuclear human *in vitro* embryo might be considered a lower life form and thus patentable because it is a single-celled entity. On the other hand, the Patent Commissioner might find that it falls within the category *of a higher life form* and thus is not patentable. There may, however, be unanticipated consequences to a finding that a pronuclear human *in vitro* embryo is a higher life form, such as implications for the use of human *in vitro* embryos in projects of research or implications on the reproductive right of a woman to terminate her pregnancy.

---

[396] *Ibid.*

[397] *Patents Act 1997*, c. 37, as amended by *Patents Act 2004*, Ch. 16.

[398] *Human Fertilisation and Embryology Act 1990*, U.K., c.37.

[399] Boult Wade Tennant, European Patent and Trade Mark Attorneys, *Patenting Stem Cells in Europe* — bulletin (August 2004) at 1. Online: http://www.boult.com/information/BulletinPrint.cfm. Accessed March 2005.

[400] *Ibid.* at 1.

[401] *Harvard Mouse, supra* note 265.

[402] The term pronuclear embryo is used to describe the unicellular human in vitro embryo. See Damario M.A. and Hammitt D.G. et al. "Embryo cryopreservation at the pronuclear stage and efficient embryo use optimizes the chance for a liveborn infant from a single oocyte retrieval" Fertil. Steril. 2000 Apr; 73(4): 767-74.

[403] The majority members of the Supreme Court in *Monsanto* were largely those members (Chief Justice McLachlin, Justices Major and Binnie) who wrote the dissent in *Harvard Mouse*. In *Harvard Mouse* the dissent rejected the approach of deciding patentability on the basis of whether the biological materials were a higher or lower life form. Although the issue in *Monsanto* was patent infringement and not patentability, the majority in *Monsanto* based it decision on patent principles.

[404] *Harvard Mouse, supra* note 265, at para. 199.

[405] *Ibid.*

The *Assisted Human Reproduction Act* (the "AHR Act") applies to sperm, eggs and to fertilized human eggs (including unicellular or pronuclear embryos) that are created for reproduction. The AHR Act also applies to supernumerary multicellular or pronuclear *in vitro* embryos donated and used for research purposes. Questions of patentability, however, are not addressed in the legislation since those would be beyond or outside its legislative scope. Its primary objective is the health and safety of both women using reproductive technologies to create a child and of any children born as a result of those technologies.

Case law

There is no case law directly on point. However, in *Daigle v. Tremblay*,[406] the Supreme Court held that a fœtus is not a person with legal rights under the Quebec *Charter*, but did not address the issue under the Canadian *Charter*. In *Morgentaler, supra*, Justice Wilson, writing one of the majority opinions and speaking for herself, noted that the state's interest in protecting the developing fœtus would only become "compelling" at some point in the second trimester of pregnancy. Until that point in the development of the fœtus, the woman's right to liberty under *Charter* gave her absolute authority to decide whether to abort.[407]

6.5.4 Discussion

The analysis and discussion relates to the following hypothetical situation:

> Researchers at a prominent university in Canada have invented a process to insert the gene for a type of bowel cancer into a pronuclear human *in vitro* embryo and to chemically suspend its further division and development. The embryo can be used in research to test pharmaceuticals in order to find a cure for bowel cancer. The research was approved and licensed by the Assisted Human Reproduction Agency of Canada under the *Assisted Human Reproduction Act*.
>
> The researchers have applied to the Patent Commissioner for a patent over the process and the genetically altered pronuclear *in vitro* embryo. Would the grant of such a patent raise any human rights issues?

In the hypothetical situation, the human embryo is being used solely for research purposes and, under the AHR Act, would be prohibited from further use in reproduction. The text of the *Charter* generally refers to rights-holders as either "everyone" or "person." The courts have held that these terms include both human beings and corporations (fictional persons), depending on the right in question. Under the common law, an *in vitro* embryo is not considered to be a person (human being) with legal rights, until it is born alive.

"Fœtus" is the term given to the implanted embryo when it reaches the eight week stage of development within a woman's uterus. If a fœtus is not a person with rights under the law and the state has no compelling interest in it, it is unlikely that the courts would find that a pronuclear *in vitro* embryo is a juridical person with rights.

On the other hand, one could argue that when the embryo exists outside a woman's body, there is no need to balance the rights of the woman with the rights of the developing embryo. For example, the Louisiana *Civil Code* grants the *in vitro* embryo legal rights, until such time as the embryo is transferred into a woman's womb. It is at the point of transfer that the two sets of rights could come into conflict and thus the embryo ceases to have any legal rights.

In the future, if Parliament or the common law assigned the pronuclear human *in vitro* embryo legal status and rights, the grant of a patent over a pronuclear *in vitro* embryo may engage human rights, such as liberty and security of the person. In addition, it might raise human rights issues related to ownership and slavery that are specifically set out in provisions under the ICCPR.

---

[406] *Daigle v. Tremblay*, [1989] 2 S.C.R. 530.

[407] *Morgentaler, supra* note 359, at 183.

The dissent in *Harvard College, supra* opined that, under section 40 of the *Patent Act*, the Commissioner of Patents could refuse to grant a patent over a human being on the basis of the *Charter*. The current legal position, however, is that a human embryo is not a human being capable of possessing legal rights and thus would not qualify for protection under the *Charter*. If the genetically altered pronuclear *in vitro* embryo met the *Patent Act*'s definition of an invention, i.e., a manufacture or a composition of matter, and the criterion for patentability, i.e., non-obvious, new and useful, the Commissioner could likely not rely on the *Charter* or any existing Canadian law to refuse a patent application under section 40 of the Act.

The Commissioner might characterize the pronuclear embryo as a higher life form and thus not patentable. Such a ruling, however, might have far reaching unanticipated consequences. It might have implications for women's reproductive autonomy rights and for research on supernumerary human *in vitro* embryos.

6.6 Conclusion

One could argue that the dissent in *Harvard Mouse, supra*, was correct in its interpretation of how questions of patentability were to be addressed under the *Patent Act*'s legislative scheme. Nowhere in the Act is there a reference to or a provision providing a distinction between higher and lower life forms for the purposes of patentability. The Act, when read as a whole, lends strong support to the argument that the patentability of subject matter should be determined on the basis of the definitions and criteria set out in the legislation. This means that there is no room under the *Patent Act* for moral and ethical questions relating to the patentability of certain animal and human materials. If Parliament is concerned with what the Commissioner patents under the Act, it has the authority to make the necessary amendments to the Act.

The courts have made it clear that judges are not well placed to address these issues. These are matters best addressed by officials who represent and are accountable to the public. In recent years, there have been calls for Parliament to amend the Act to clarify the patentability of certain biological materials in Canada, such as human *in vitro* embryos. The CBAC has issued two reports to Parliament suggesting a number of amendments to the Act, but Parliament has remained silent.

The apparent absence of political will to address these difficult questions, coupled with a possible expansion of the scope of patentability, arguably may result in the granting of property rights over excised human materials that differ little from the same materials in the human body. The rationale for denying property rights to individuals over their excised bodily materials may no longer be defensible when biotechnology companies can attain such rights with minimal inventive effort.

The impact on human dignity is difficult to predict. Some would argue that the ability to sell and profit from excised bodily materials will enhance their subjective feelings of self-respect and self-worth. Others would be concerned that the commercialization and commodification of the human body, as the site of the soul and personhood, will de-value and cheapen life and ultimately, diminish human dignity. Although human dignity is not a free-standing human or constitutional right, it is the underlying value of most of the fundamental human rights at the international level and domestically in the *Charter*.

Intellectual property rights in the form of patents were designed to grant to the inventor a monopoly to capitalize on his or her invention. Patent rights allow the patentee to exclude others from using, selling or making the patented invention in return for disclosing information about the invention to further knowledge within society. This social bargain works well when the invention is inanimate materials, e.g. metal or plastic. One can argue, however, that when these same patent rights apply to processes involving or to human biological materials and genetic therapies, the unrestricted ability to exclude all others from using, making or selling may be too broad and may no longer serve the best interests of society.

The chapter illustrates that, in order to engage human rights under the *Charter*, government action must be implicated. It is unlikely that the grant of a patent by the state would engage any human rights since it only provides the patentee with a right to exclude others from using, making or selling the patented invention. In the case of patented human biological materials, it would require the presence of a number of facts before one could argue that human rights are engaged.

The hypothetical scenarios were designed with the objective of raising human rights issues. The likelihood of such scenarios occurring is impossible to predict. While it is possible to conclude that the patenting of human biological materials raises serious ethical and moral concerns, because the *Charter* only applies to government action it requires the patentee's assertion of his or her rights under the *Patent Act* to engage the *Charter*. It is clear that reliance on the *Charter* to deal with the ethical and moral issues that will continue to arise from the patenting of human biological materials is problematic. The time has come for Parliament to amend the *Patent Act* to exempt certain human biological materials that society considers unpatentable.

Government of Canada Gouvernement du Canada

A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 7

Biotechnology, Rights and Traditional Knowledge

Canada

A Brave New World: Where Biotechnology and
Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Chapter 7

Table of Contents

7.1 Introduction 7–1

7.2 Overview: Biotechnology and Traditional Knowledge 7–2

7.3 Public Policy Considerations Respecting TK and Biotechnology 7–5

7.4 Rights and Traditional Knowledge 7–8

7.4.1 Framing a Right to Traditional Knowledge 7–9
7.4.2 The International Level 7–10
7.4.3 The Domestic Level 7–26

7.5 Options to "Respect, Preserve and Maintain" TK 7–38

7.6 Conclusion 7–41

Chapter 7

Biotechnology, Rights and Traditional Knowledge

Stefan Matiation

7.1 Introduction

There are two major issues related to the impact of biotechnology on indigenous interests that can be investigated from a rights perspective. The first concerns the protection and use of indigenous traditional knowledge, innovations and practices. The second relates to concerns, drawn from historic and contemporary examples of targeted ill treatment, about the possibility that indigenous people are vulnerable to discrimination in the conduct of biotechnology research on human subjects.[1] Both of these matters are linked at a fundamental level to the question: what is the appropriate balance to be sought between the interest in recognizing and respecting indigenous cultural, political, economic and social integrity and that of encouraging research activities and scientific advances in the field of biotechnology that might be beneficial to society as a whole? This chapter focuses solely on the first issue, i.e., the protection and use of indigenous traditional knowledge. It does not include an answer to this question, but is based on an assumption that might inform one: a rights based analysis can help provide guidance to governments in finding the appropriate balance in relevant law and policy making.

An overview of the issue of biotechnology, rights and indigenous people is set out in this chapter, with a focus on the first of the two topics identified above – that concerning rights to indigenous knowledge, innovations and practices relevant to biotechnology applications of non-human biological resources. The concept of "rights" used here includes human rights to which every individual is entitled, as well as indigenous, or, using Canadian terminology, aboriginal rights that are held by indigenous individuals or peoples on the basis of their indigenous status.[2] Due to the nature of indigenous knowledge, innovations and practices, the primary focus is on indigenous rights.[3] For this reason, this chapter is quite different from the others in this compendium.

---

[1] Human genetic resources are of interest for biotechnology research. It is believed that the study of the human genome will yield significant health benefits that will enrich the lives of all people. However, research on human subjects, or on the genetic material of human subjects, particularly at a level that could lead to the alteration of genetic material of individuals, groups or the human species, raise a host of challenging legal and ethical issues. Indigenous people have expressed grave concerns about the possibility that they will be targeted for discrimination during or as a result of such research, including possibly in the determination of who is part of a particular indigenous community. Since they often represent a relatively homogeneous gene pool, indigenous communities are regarded as a good focus for human genetic research. The Human Genome Diversity Project (HGDP), an international project which involves the collection and comparison of genetic material from diverse ethnic groups worldwide, including in particular indigenous peoples, has been met with concern by NGOs, some of which represent indigenous people. Public pressure has significantly delayed this project. Indeed, to date no human genetic data collection has been undertaken by the HGDP, except by its regional committees in China and Southwest Asia, which have collected some samples in their regions. (Personal communication with Henry Greely, Morrison Institute, Stanford University, HGDP North American Regional Committee, November 24, 2003) The coordinators of the HGDP are now encouraging that any sampling be undertaken only in accordance with ethical guidelines addressing indigenous peoples' and local community concerns. The guidelines that have been developed for this purpose are available at http://www.stanford.edu/group/morrinst/hgdp/protocol.html, last viewed on March 18, 2004. Other materials on this issue include the following: Steve Olson, "The Genetic Archaeology of Race", *The Atlantic Monthly*, April 2001, available at http://www.theatlantic.com, last viewed on November 24, 2003; Henry Greely, "What About the Other Human Genome Project? The Perils and the Prospects of the Human Genome Diversity Project", on file; UNESCO *International Declaration on Human Genetic Data*, adopted unanimously by the UNESCO General Conference on October 16, 2003; *Declaration of the Indigenous Peoples of the Western Hemisphere Regarding the Human Genome Diversity Project*, available at http://www.indians.org/welker/genome.htm, last viewed on October 21, 2003; M. Foster, "The Human Genome Diversity Project and the Patenting of Life: Indigenous Peoples Cry Out", (1999) 7 *Canterbury Law Review*, 343; UN Commission on Human Rights, *Human genome diversity research and indigenous peoples*, E/CN.4/Sub.2/AC.4/1998/4.

As is discussed further below in Section 7.3, the core rights assertion at issue can be framed for the purposes of this discussion as follows: *indigenous peoples have the right to own and control access to, and the use of, traditional knowledge, innovations and practices*. This assertion may be made both in relation to knowledge, innovations and practices that are only known to an indigenous community, and in relation to that which is already in the public domain[4], which is a more challenging matter to address. The underlying question to be considered is: do indigenous people have this right under international or Canadian law? If they do, this would have implications for biotechnology-related policy and law making.

It should be noted at the outset that the question of the existence of a right to control TK is highly speculative – there is little directly applicable law on the topic that can be used to find an answer. Indeed, it is even difficult to predict whether or how a TK claim might be framed in litigation before a domestic court, for example. However, TK is an emerging issue in the field of indigenous rights. More likely than not, international and domestic developments in relation to it will continue to grow in importance for Canada in the coming years. Accordingly, consideration of a rights dimension to TK issues related to biotechnology, however tentative, is useful.

The chapter begins with an overview that includes a description of the term "traditional knowledge" and of relevant public policy considerations. This is followed by a section investigating whether a basis exists in law to ground assertions that indigenous peoples have a right to own and control their knowledge, innovations and practices. International law and Canadian domestic law are addressed in turn in this regard. Finally, options that could be used to address indigenous interests in their knowledge, innovations and practices are identified and briefly discussed, with a view to potential gaps in existing approaches.

7.2 Overview: Biotechnology and Traditional Knowledge

The relationship between biotechnology and indigenous knowledge, innovations and practices can be illustrated with the following example.

The San, an indigenous group that live in parts of southern Africa (also referred to as Bushmen) have collected and used the sap of the *Hoodia gordonia* plant for centuries as a hunger suppressant and energy source. In 2001, the San became aware that the Council for Scientific and Industrial Research (CSIR) of South Africa had identified the active ingredient of the Hoodia, which it used as the basis for a patent. The CSIR patent was later purchased by Pfizer in the U.S. for development as the basis for an appetite suppressing drug. Although they initially received no benefits from the scientific application of information about the Hoodia, and were not initially consulted by CSIR, the San did eventually convince the organization to enter into benefit sharing negotiations with them. CSIR acknowledged that they used San traditional knowledge as a basis for their research into the Hoodia, and, in 2003, agreed to enter into an agreement whereby the San will receive payments of between 8 and 12 million Rand over four years, plus 6% of the royalties that are received by CSIR from Pfizer, should it develop a marketable product from the patent.[5]

---

[2] In keeping with international practice, the term "Indigenous" is used in this chapter when referring to Indigenous peoples or individuals in discussions about the international context. There is no widely accepted definition of "Indigenous peoples" at international law. However, for the purposes of this chapter, it is sufficient to say that the term includes the aboriginal peoples of Canada, which is the term used here when referring to the domestic context. Pursuant to section 35(2) of the *Constitution Act, 1982*, the aboriginal peoples of Canada includes the "Indian, Inuit and Métis peoples of Canada".

[3] There is some debate about how the concept of indigenous or aboriginal rights relates to the concept of human rights. This chapter does not address the issue. Instead, the term "human rights" is used to describe rights to which everyone is entitled (although some may be specific to minorities, women, children, etc.) and "indigenous rights" are used to refer to rights to which only indigenous people are or would be entitled. The term "aboriginal rights" is more specific. Canadian domestic law describes these rights, which are discussed in Part 3 below on TK at the domestic level.

[4] Although mostly used in a copyright context, the concept of public domain is used in this text to also include subject matter that is not patentable, either anymore or in the first place.

[5] "Traditional Knowledge of the San of Southern Africa: *Hoodia gordonia*", presentation prepared by Victoria Geingos and Mathambo Ngakaeaja, Working Group of Indigenous Minorities in Southern Africa for the Second South-South Biopiracy Summit, August 22–23, 2002, Johannesburg, South Africa. [source]

The San were represented by the South African San Council in their negotiations with CSIR. This organization, together with the regional Working Group of Indigenous Minorities in Southern Africa, which represents indigenous groups in South Africa, Botswana, Namibia and Angola, is focused on protecting San heritage through a combination of community based education and capacity building projects, human rights advocacy and training, and litigation respecting rights to traditional lands.[6] The Council used rights based lobbying to convince the CSIR that it should address benefit sharing with the San.

As indicated in the Hoodia case, biological resources that hold promise for biotechnology research, and information about their potential applications, is often "discovered" through the study of the knowledge, innovations and practices of indigenous people. Indigenous groups, biotechnology companies and researchers, and States with large biotechnology industries or research potential all share an interest in biological resources and in information about its applications.[7] This both raises concerns for indigenous communities, and may provide them with some opportunities. The ability of indigenous groups to take advantage of these opportunities may be linked to recognition of and respect for indigenous rights.

"Biotechnology" is defined in the *Canadian Environmental Protection Act* as:

> ...the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.[8]

... and, for an international example, in the *Convention on Biological Diversity* (CBD), to which Canada is a Party, as:

> ... any technological application that uses biological systems, living organisms, or derivates thereof, to make or modify products or processes for specific use.[9]

Classical biotechnology – the alteration of the frequency of genes over successive generations by crossing different species or varieties through hybridization – is based on pioneering work undertaken by Gregor Mendel in the 19th century concerning the science of heredity. Modern biotechnology emerged in the latter part of the 20th century. It involves techniques that operate at the cellular or molecular level to modify the genetic code of organisms. These techniques allow scientists to exchange genetic information between micro-organisms, plants and animals (including humans).[10]

The agricultural, pharmaceutical and environmental sectors of the biotechnology industry hope to find and modify biological resources found in plants, animals and micro-organisms to develop new products, medicines, processes, and applications. Many of the innovations that are developed will be protected through the intellectual property rights regime. Researchers, many of whom work for government funded institutes, are particularly interested in the biological resources to be found in mega-diverse regions of the world – those regions characterized by a high degree of biological diversity such as the Amazon basin – as well as those found in harsh or unique environments, including parts of Canada. Many of the regions and environments that attract the attention of researchers have for millennia been inhabited by indigenous peoples, who have long developed techniques that fall within the definitions of biotechnology set out above – observing, modifying and applying living organisms for a variety of purposes such as food production, medicines, and environmental management.[11]

---

[6] See the websites of the Working Group of Indigenous Minorities in Southern Africa and of the South African San Council, http://www.wimsareg.org and http://www.san.org.za, respectively, last viewed on March 24, 2004.

[7] The convergence of interest between governments, companies and indigenous peoples in biological resources is not unlike a similar convergence of interest in respect of other natural resources like minerals, forests, and oil and gas. Efforts that have been undertaken to resolve the conflicts inherent in this convergence in relation to the latter natural resources through the identification of competing rights and interests at stake and of possible mutually beneficial solutions may therefore offer useful guidance for the resolution of conflicts in relation to biological resources.

[8] *Canadian Environmental Protection Act*, 1999, c.33, s. 3(1).

[9] *Convention on Biological Diversity*, available at http://www.biodiv.org, last viewed March 15, 2004, Article 2.

[10] This paragraph is drawn from *Biotechnology: A reference tool for DOJ practitioners*, 2003, at 4 and 5.

[11] In a short book comparing how economic advantages of North and South America have shifted from a situation in which the South was comparatively "richer" to one in which economic wealth favours the North, Felipe Fernandez-Armesto briefly discusses the history of maize production and trade among indigenous groups, including the application of plant breeding techniques to develop new varieties to suit local conditions. *History of the Americas*, 2003.

What is Traditional Knowledge?

Through an intimate relationship with their natural surroundings and long intergenerational practice, indigenous communities in all parts of the world have developed knowledge, innovations and practices that have traditional and contemporary applications. The term "traditional knowledge" or "TK" is used in this chapter as a helpful short hand for a broad conception of knowledge, innovations and practices that have roots in the past, but an evolving nature.[12]

The focus of this chapter is on TK that is most relevant to biotechnology, such as that used to locate or identify biological resources that might yield profitable patents, and, more importantly, to determine the possible uses of those resources, as in the Hoodia example described above. However, it is important to bear in mind the full breadth of matters the term refers to. TK encompasses a variety of matters that go well beyond the scope of the field of biotechnology. For indigenous peoples, TK issues are about more than knowledge — they are about culture, customary laws and practices, social organization, relationships with lands and resources, and collective self-determination.[13]

The term "traditional knowledge" has not been the subject of a widely accepted definition internationally or domestically. Instead, the term has been applied in different ways to suit the many different contexts and diffuse policy frameworks within which it is discussed. The Secretariat of the World Intellectual Property Organization (WIPO) uses the term to refer to "tradition-based literary works, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields."[14] The Secretariat has described "tradition-based" as referring to:

> ... knowledge systems, creations, innovations and cultural expressions which: have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment.[15]

The application of the word "traditional" to indigenous knowledge, innovations and practices in this chapter should not be taken to mean that indigenous knowledge is frozen in a pristine time prior to contact with non-indigenous societies.[16] The evolving nature of TK is explained in the following passage:

> My focus here will be the legal defence of indigenous science. The familiar term, "traditional knowledge", implies a body of relatively old data that has been handed down from generation to generation essentially unchanged. Operating on that assumption, the main focus of Western research has been taxonomic: identifying plants and animals used by indigenous peoples, recording their local names, and cataloguing their reported uses. Local knowledge of the useful pharmacological and physical properties of native species is presumed to have been assembled a long time ago.... [and] can be elicited from any capable local informant. Within any community, however, people vary greatly in what they know. There are not only differences between ordinary folks and experts, such as experienced healers, hunters or ceremonialists; there are also major differences of experience and professional opinion among experts, as we should expect in any living, dynamic knowledge system that is continually responding to new phenomena and fresh insights.[17]

Describing traditional knowledge as a category of knowledge, however broad, does not do justice to the significance that TK holds for indigenous communities. TK is often described in relation to rights — "rights to land, territory and resources; rights to full disclosure and prior informed consent; rights to cultural integrity and customary practices; and rights to equitable benefit-sharing and control over access to traditional resources."[18]

---

[12] "Traditional knowledge" is not necessarily the preferred term used by Indigenous peoples to refer to the breadth of matters the term is intended to cover. Sakej Henderson has written about the importance of maintaining aboriginal languages and world views, and risks of assimilating aboriginal thought into English, French or Spanish language traditions. See "Governing the Implicate Order: Self-Government and the Linguistic Development of Aboriginal Communities", 1993, copy on file.

[13] The right of self-determination is discussed in more detail below.

[14] WIPO/GRTKF/IC/3/9, at 11, available on the website of the World Intellectual Property Organization at http://www.wipo.org, last viewed March 15, 2004.

[15] *Ibid.*

[16] John Borrows has critiqued this idea. See, for example, *Recovering Canada: The Resurgence of Indigenous Law*, 2002, especially Chapter 3.

[17] R. Barsh, "Defending Indigenous Science from Biopiracy: A Choice-of-Laws Approach, at 3. Unpublished. Copy on file.

Traditional knowledge is regarded as intimately connected to land and to culture. Russel Barsh offers that this is not a connection to "land in general, but to particular landscapes, landforms and biomes where ceremonies are properly held, stories properly recited, medicines properly gathered and transfers of knowledge properly authenticated."[19] As a cultural matter, TK cannot easily be separated from the languages within which it is expressed, and the worldview of the community that holds and uses it. Indeed, Barsh suggests that the greatest threat to TK arises within indigenous communities themselves which he thinks must carefully maintain their traditional languages and cultural practices in order to preserve their traditional knowledge and develop new innovations and applications for it.[20]

Finally, traditional knowledge is not something that must be isolated from the processes of learning and knowing found in the non-indigenous community. In this regard, John Borrows notes:

> There is contemporary worth in Indigenous traditions that consider all the constituent parts of the land to be related. While I regard this knowledge as imperfect and incomplete, it also insightful and wise. There is much to be gained by applying this knowledge within Aboriginal communities and within Canada as a whole. Our intellectual, emotional, social, physical, and spiritual insights can simultaneously be compared, contrasted, rejected, embraced, and intermingled with those of others.[21]

7.3 Public Policy Considerations Respecting TK and Biotechnology

Access to TK is important to society as a whole because it is often the basis for products that have wide and beneficial applications. Traditional knowledge has played a critical role in the development of important agricultural, industrial and pharmaceutical applications. There is a broad social interest in promoting research about life saving drugs, for example, by providing a regulatory environment that is conducive to the encouragement of the allocation of sufficient resources to efforts to leave no stone unturned in attempts to find organisms and applications that could yield fruitful results.

Legal regimes currently in force internationally and in Canada tend to favour the promotion of innovation in biotechnology research by rewarding creators and inventors who share their novel creations and applications. "Modern thinking on [intellectual property rights systems] is that they are socially agreed-upon incentives designed to encourage innovation as well as public disclosure of information about those innovations."[22] Under intellectual property regimes, private property rights are conferred to reward the investment in research and development by inventors and creators, and to encourage the public disclosure of inventions or creative works. In order to balance this interest with that of maintaining the public domain needed to promote a free flow of ideas and information for the use of all inventors and creators, this private property right reward is limited in duration.[23]

Although it does not necessarily exclude the recognition of intellectual property rights in TK applications or innovations, the intellectual property regime has not developed to date with TK in mind, and accordingly does not address many of its unique characteristics, or indigenous peoples' perspectives about the way it should be held, shared and respected. For example, instead of being the property of an individual creator or inventor, traditional knowledge is understood to be a community asset that is held and applied for the benefit of the members, although particular people in a community may be recognized as experts in a particular type of knowledge, or as holders of particular roles in its protection or dissemination. Further, traditional knowledge is not viewed as time limited. Instead it is seen as exclusive and held for time immemorial. Indigenous peoples' interests in traditional knowledge are therefore not necessarily well served by the intellectual property rights regime.[24]

---

[18] G. Duffield and G. Posey, *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous and Local Communities*, 1996, at 211 to 212.

[19] Barsh, *supra* note 17, at 5. See also L. Whitt, M. Roberts, W. Norman and V. Grieves, "Belonging to Land: Indigenous Knowledge Systems and the Natural World", (2001) 26 Okla. City U.L. Rev. 701.

[20] Barsh, *supra* note 17, at 25. See also Sakej Henderson, *supra* note 12; and M. Battiste, *Maintaining Aboriginal Identity, Languages and Culture in Modern Society*, Royal Commission on Aboriginal People, 1993.

[21] Borrows, *supra* note 16, both quotes at 147.

[22] D. Downes, "How Intellectual Property Could be a Tool to Protect Traditional Knowledge", (2000) 25 Colum. J. Envtl. L. 253 at 261.

[23] *Ibid.*

From a practical perspective, traditional knowledge is controlled by its holders. An indigenous person or group holding traditional knowledge can protect that knowledge by deciding not to share it with outsiders, such as biotechnology researchers. If this were the whole story, there would be no need for a discussion about the rights dimension of TK, but the matter is not so simple.

The traditional knowledge of indigenous groups is often used without their consent – for example by researchers engaged in bioprospecting or so-called "bio-piracy" – to gain access to valuable genetic or biological resources.[25] The unauthorized use of TK is common partly because a considerable amount of indigenous knowledge has already been collected and described by anthropologists, ethnobotanists and others.[26] Further, with possible exceptions respecting the sacred, indigenous communities have not always tried to keep their knowledge secret from those interested in hearing about it. The extent to which traditional knowledge is in the public domain makes it difficult to protect through the existing legal tools that are available to secure intellectual property rights, such as patent law or copyright.[27] At the same time, it is possible that a patent holder that uses traditional knowledge as a basis for a patent may be able to use defensive measures under patent protection schemes to bar indigenous holders of the knowledge from using it for commercial or possibly non-commercial purposes. The result is a two fisted blow – indigenous people may not be able to use intellectual property law to their advantage, and might also have it used against their interests.

An additional issue concerns biological resources that are collected on lands traditionally used or occupied by indigenous people. In many cases this is easily done without the approval and involvement of the relevant community. This is a matter of concern for indigenous groups who argue that they should receive benefits when genetic resources are gathered on their traditional lands in the same way that landholders – the State or private parties – might receive benefits by controlling access to certain lands. It should be noted, however, that the lands in which indigenous peoples assert they have an interest based on traditional use or occupancy often encompass much more acreage than governments are prepared to recognize or accommodate, often because such lands have legitimately been taken up for valid reasons.[28]

---

[24] According to the Royal Commission on Aboriginal People (RCAP), "Under Canadian law, almost all Traditional Knowledge is already considered to be in the public domain and thus beyond protection. In the few cases where TK benefits from protection and where present law applies, the protection is short-lived." (*RCAP Report*, 1996, Volume 3, Chapter 6, Section 1.3 at 596. Available at http://www.ainc-inac.gc.ca/ch/rcap/index_e.html, last viewed April 1, 2004) See also R. Coombe, "Intellectual Property, Human Rights & Sovereignty: New Dilemmas of Indigenous Knowledge and the Conservation of Biodiversity", (1998) 6 *Indiana Journal of Global Legal Studies* 59, Dutfield and Posey, supra note 18, J. Githaiga, "Intellectual Property Law and the Protection of Indigenous Folklore and Knowledge", (1998) 5 *Murdoch University Electronic Journal of Law*, 1, available at: http://www.murdoch.edu.au/elaw/issues/v5n2/githaiga52.txt, last viewed October 1, 2004, L. Whitt, "Indigenous Peoples, Intellectual Property and the New Imperial Science", (1998) 23 Okla. City U.L. Rev. 211; s. Ragavan, "Protection of Traditional Knowledge", (2001) 2 Minn. Intell. Prop. Rev. 1; D. Gervais, "Spiritual but not Intellectual? The Protection of Sacred Intangible Traditional Knowledge", (2003) 11 Cardozo J. Int'l & Comp. L. 467; and G. Dutfield, "Intellectual Property Rights and Development", *UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development*, 2003, available at: http://www.ictsd.org/pubs/ictsd_series/iprs/PP.htm, last viewed March 30, 2004.

[25] "Bio-piracy has been defined as the process through which the rights of indigenous cultures to genetic resources and knowledge are 'erased and replaced for those who have exploited indigenous knowledge and biodiversity'." In C. Correa, *Traditional Knowledge and Intellectual Property: A Discussion Paper*, 2001, at 4. In M. DeGeer, "Biopiracy: The Appropriation of Indigenous Peoples' Cultural Knowledge", (2003) 9 New Eng. Int'l & Comp. L. Ann. 179 at 180, it is defined as "the illegal appropriation of life — micro-organisms, plants, animals (including humans) and the traditional cultural knowledge that accompanies it." In essence, the term refers to the misappropriation of TK or genetic resources. "Bio-prospecting" is a term referring to the search for such resources.

[26] Discussed in Downes, *supra* note 22, Correa, *supra* note 25, and in M. DeGeer, *supra* note 25, among other sources.

[27] It should be noted in addition that once a patent is granted, the patent holder can take defensive measures to stop others from using the knowledge concerned. Litigation or the threat of litigation could be used by a patent holder to bar further use of the knowledge by the indigenous group that initially held it for commercial or possibly other purposes.

[28] It should also be acknowledged that indigenous claims to land are often ignored by governments in many countries and that the traditional lands of indigenous peoples have in the past and continue to be taken from them for illegitimate purposes. Reconciling indigenous land claims with other land use priorities in reasonable and fair ways is a challenge world wide. The UN Commission on Human Rights Sub-Commission on the Promotion and Protection of Human Rights has requested Erica-Irene Daes to conduct studies on indigenous peoples and their relationship to land and on indigenous peoples and natural resources. Daes has produced some materials in this regard: E/CN.4/Sub.2/2001/21; E/CN.4/Sub.2/2002/23; and E/CN.4/Sub.2/2003/20. To date, this work has been disappointing — drawing selectively upon certain materials while ignoring important principles of territorial integrity and State sovereignty over natural resources. These reports do not draw upon significant policy and legal measures that are used in Canada to reconcile competing interests in relation to land use and land ownership issues, many of which could be modeled by other countries.

Not only does the unauthorized use of traditional knowledge or of genetic resources found on the traditional lands of indigenous peoples often mean that they lose out on benefits arising from their utilization, sacred knowledge and plants, animals and other organisms that are important to indigenous groups may be misused to the detriment of the cultures, economies and systems of social organization that are the foundation of their communities. Indeed, concerns about the misuse of the sacred and about negative impacts on the community and environment often outweigh economic considerations. It is sometimes argued that regardless of any relevant economic considerations, indigenous communities should be able to prohibit access to certain genetic resources and associated TK for reasons that are important to them.[29]

According to the International Chamber of Commerce and the Biotechnology Industry Organization, the biotechnology industry appears to be prepared to take the concerns of indigenous peoples more seriously.[30] Companies that are active in field research are not responsible for the resolution of broader claims that are made by indigenous groups related to rights to traditional lands, the protection of cultural heritage and to the right to self-determination – all of which are issues squarely within the authority of State governments to consider. However, the acknowledgement by some such companies that they should, for example, only obtain traditional knowledge with the prior informed consent of the knowledge holders and ensure that benefits flow to indigenous knowledge providers, suggests that the view that ethical and rights-related considerations are triggered by the utilization of TK is growing in acceptance.[31]

On the other hand, there is no doubt that indigenous claims raise concerns for the biotechnology industry, which is well served by a system that promotes fairly easy and inexpensive access to biological resources in the interests of the promotion of innovation and research.[32] A particular area of concern relates to any recognition of rights to control traditional knowledge that is already in the public domain. The isolation of Quinine, a leading anti-malarial drug, for example, was based on information shared by indigenous communities with European explorers in the 17th century regarding the use of the bark of the *Chincona ledgeriana* tree to treat malaria.[33] Recognition of a right to traditional knowledge related to matters that have long been in the public domain would raise some possibly insurmountable difficulties.

Efforts to address the concerns that indigenous people have with the utilization of their traditional knowledge and of genetic resources on lands they traditionally used or occupied (or actually own) will likely involve the striking of a balance between public policy goals respecting the encouragement of innovation and the free flow of ideas and information, and those respecting the interest in finding ways to respect indigenous peoples and to promote and support their cultural, social, political and economic goals. An analysis of indigenous rights to TK could provide helpful guidance in finding that balance.

---

[29] Intellectual property law can provide offensive means to protect traditional knowledge from misappropriation, not only defensive ones. For example, an indigenous group could use intellectual property principles and procedures to bar the commercial monopolization of their knowledge by others. Barsh notes that to "be patentable, … knowledge must be novel in some way. An idea that is already being used somewhere, or would be obvious to anyone familiar with the particular branch of technology concerned, is not eligible for patent protection." In the absence of satisfactory screening procedures to determine whether an applicant has disclosed reliance on TK, however, the resources needed to monitor the plethora of patents that are processed, for example, by the US Patent and Trademark Office, can place offensive measures beyond the reach of traditional knowledge holders. (Barsh, *supra* note 17) These measures do not address issues about confidentiality of traditional knowledge. In relation to this, Christie suggests that any law reform initiatives aimed at addressing indigenous concerns about the misappropriation of traditional knowledge should create a "wall of secrecy" around aboriginal culture, rather than a "marketplace of ideas" promoting its utilization. (G. Christie, "Aboriginal Rights, Aboriginal Culture, and Protection", (1998) 36 Osgoode Hall L.J. 447 to 484 at para. 92. On the other hand, Borrows discusses the importance of recognizing the interdependent nature of "Aboriginal/non-Aboriginal relationships" as an element of enhanced Canadian unity. (See Borrows, *supra* note 16, especially Chapter 6.) This view would appear to favour more of an exchange of knowledge and ideas than the "wall of secrecy" suggested by Christie. The Royal Commission on Aboriginal Peoples states that "In asserting claims to their traditional knowledge, Aboriginal people are not trying to retreat from the world… Aboriginal people are willing to share the wealth of their cultures and … knowledge… At the same time, they want to ensure that their knowledge is used appropriately… They also want fair compensation…", *RCAP Report*, 1993, Chapter 6, Volume 3, Section 1.3, *supra* note 24.

[30] See the websites of the International Chamber of Commerce at http://www.iccwbo.org, last viewed March 16, 2004, and of the Biotechnology Industry Organization at http://www.bio.org, last viewed March 16, 2004, for information about the views of these organizations. In particular, see the ICC discussion paper called "Protecting traditional knowledge" and a letter from L. Val Giddings, Vice President for Food and Agriculture, Biotechnology Industry Organization to Claudia McMurray, Deputy Assistant Secretary for Environment, US Department of State, dated February 5, 2004.

[31] See "Biotechnology's Foreign Policy", speech delivered by C. Feldbaum, President of the Biotechnology Industry Organization to BIO 2002, the International Biotechnology Convention and Exhibition on June 10, 2002 in Toronto. Available at http://www.bio2002.org/press/cart.asp, last viewed on March 11, 2004.

[32] BIO letter, *supra* note 30.

[33] *Ibid.*

7.4 Rights and Traditional Knowledge

Chapter 1 of this paper provides an overview of the major domestic and international sources of human rights law, as well as a discussion of existing and evolving human rights concepts relevant to biotechnology. That overview need not be repeated here. Instead this section will focus on a discussion of possible sources of rights relevant to traditional knowledge. As indicated above, the concept of "rights" used in this chapter includes human rights to which every individual is entitled, as well as indigenous, or, using Canadian terminology, aboriginal rights. Due to the nature of traditional knowledge, and the fact that international and domestic indigenous rights are addressed differently under the law than human rights, and are not discussed elsewhere in this paper, the focus of the discussion is primarily on indigenous rights.

Subject to certain challenges posed by the collective nature of some of the rights claimed, or in fact held, by indigenous groups in Canada and internationally,[34] indigenous individuals are entitled to all of the same human rights as any other individuals under the law, at least in theory if not in practice. All indigenous individuals are entitled to the same legally recognized universal human rights as every other individual; indigenous women are entitled to all the same legally recognized women's rights as non-indigenous women; indigenous children are entitled to all of the same legally recognized children's rights as non-indigenous children; aboriginal individuals in Canada are entitled to all of the human rights protections as provided in the *Canadian Charter of Rights and Freedoms*.

A statement that indigenous individuals are entitled to the same human rights as everyone else places a comfortable gloss on a much more difficult story. Indigenous people are often targeted for discriminatory treatment.[35] Discrimination is experienced by indigenous individuals directly and by indigenous people as a group on a systemic basis. For example, aboriginal people in Canada have a long and difficult experience with discrimination.[36] This experience has contributed to a situation in which aboriginal people continue to be "on the bottom of every list where it's a bad place to be, such as regarding life span, income, and so forth, and on top of every list where that is the worst place to be, such as concerning unemployment, suicide, diabetes and the like."[37]

---

[34] This statement is made because conflicts can arise between individual rights to which all indigenous individuals are entitled and indigenous rights that are held by collectivities. At the international level, a widely accepted mechanism to resolve such conflicts does not exist. Indeed, some States participating in the sessions of the UN Working Group on the Draft Declaration on Indigenous Rights have objected wholeheartedly to any recognition of collective rights in that instrument, a position that stymies progress considerably in that process. Germany and Japan, for example, have suggested that they will not support the adoption of a declaration describing collective rights. Canada does not share the views of these States, preferring instead to clarify which rights in the declaration can be described in collective terms and which as individual rights. A framework to address conflicts between collective aboriginal rights and individual human rights does exist in the Canadian Constitution, but is undeveloped in the case law. This framework is discussed in Part 2 below. Cases addressing conflicts between community and individual interests include: *Corbière v. Canada* [1999] 2 S.C.R. 2003 and *Re. Desjarlais and Piapot Band No. 75*, [1990] 1 CNLR 39 (Fed. CA). See also S. Matiation, *Discrimination, HIV/AIDS and Aboriginal People*, 1999, for a discussion about a specific situation in which a misperceived conflict can arise. Available at http://www.aidslaw.ca, last viewed November 19, 2003.

[35] In its resolution E/CN.4/2001/57, the Commission on Human Rights decided to appoint a special rapporteur on the situation of human rights and fundamental freedoms of indigenous people. The first report of the Special Rapporteur, Mr. Rodolfo Stavenhagen, was submitted in 2002 as document E/CN.4/2002/97. In that report, the major human rights issues confronting Indigenous peoples, in the view of the Special Rapporteur, are identified.

[36] Canada's *Statement of Reconciliation* to aboriginal peoples includes the following paragraph: "Sadly, our history with respect to the treatment of Aboriginal people is not something in which we can take pride. Attitudes of racial and cultural superiority led to a suppression of Aboriginal culture and values. As a country, we are burdened by past actions that resulted in weakening the identity of Aboriginal peoples, suppressing their languages and cultures, and outlawing spiritual practices. We must recognize the impact of these actions on the once self-sustaining nations that were disaggregated, disrupted, limited or even destroyed by the dispossession of traditional territory, by the relocation of Aboriginal people, and by some provisions of the *Indian Act*. We must acknowledge that the result of these actions was the erosion of the political, economic and social systems of Aboriginal people and nations." Available at: http://www.ainc-inac.gc.ca/gs/rec_e.html, last viewed March 25, 2004. The history of the relationship between aboriginal and non-aboriginal Canadians is described at length in the 1996 Report of the Royal Commission on Aboriginal Peoples, Volume 1, available at: http://www.ainc-inac.gc.ca/ch/rcap/sg/sgmm_e.html, last viewed on March 25, 2004.

[37] B. Morse, "Symposium: Tribal Sovereignty: Back to the Future? A View From the North: Aboriginal and Treaty Issues in Canada", (1995) 7 St. Thomas L. Rev. 671 at 674. The fact that significant disparities continue to exist between the well-being of registered Indians in Canada and other Canadians is confirmed in the following report: D. Beavon and M. Cooke, "An Application of the United Nations Human Development Index to Registered Indians in Canada" in *Aboriginal Conditions*, ed. J. White, D. Beavon, and P. Maxim, 2003.

Indigenous people also assert rights that differentiate them from non-indigenous people. Differentiated indigenous rights are linked to the particular history of indigenous people, their relationship to land and traditional activities, their collective integrity and to their unique cultures and practices. Although differentiated indigenous rights are found both in Canadian domestic law and in a small number of international instruments (some of them nascent), it can be challenging for legal systems based on western liberal theory to fully integrate and apply them.

Patrick Macklem suggests that both undifferentiated and differentiated rights have appeal for indigenous people. Undifferentiated rights attach to indigenous people "not on account of their indigenous difference but instead because they relate to aspects of identity that are seen as constituting fundamental attributes of all human beings."[38] The appeal of differentiated rights "lies in the intuition that there is something about indigenous difference that merits legal protection".[39] Incongruities between the rights that indigenous people are entitled to as human beings and those rights they are entitled to as indigenous peoples pose significant conceptual challenges, particularly in relation to conflicts between individual and collective rights, a theme that is often repeated in discussions about indigenous rights.[40]

This section is divided into three parts. The first frames the core right to traditional knowledge that is asserted by indigenous peoples, based on an admittedly very narrow sample of representative statements and declarations. The second part addresses rights and TK at the international level. The third addresses the domestic. With respect to parts two and three, it is first helpful to be aware of: (1) the context within which issues about biotechnology, rights and traditional knowledge are arising, and (2) the legal framework within which indigenous rights are being addressed. Background sections addressing these matters in each part are followed by discussions focused on the main topic of this chapter — whether there is a basis in law for an indigenous right to own and control TK.

7.4.1 Framing a Right to Traditional Knowledge

As mentioned above, it is difficult to frame a right to traditional knowledge. This is partly because of its nature — TK is viewed as intimately connected to indigenous traditional lands, cultures and world views. Separating a "TK right" from other rights asserted by indigenous peoples is therefore challenging. Further, in Canadian law in particular, the determination by the courts of whether a right to TK exists will be fact and site specific. Finally, as indicated in the discussion below, a widely accepted iteration of a "right to TK" does not exist in international or Canadian law.

In order to frame the right at issue for the purposes of this paper at least, it is helpful to draw upon a few samples of claims that have been made by indigenous representatives themselves. The three identified here amount to a very narrow selection, but are instructive nonetheless. Although such statements and declarations have no binding force they do contribute to the development of relevant principles that may influence international and domestic policy and law makers.[41]

In June 1993, indigenous people representing a number of groups met in New Zealand for the First International Conference on the Cultural and International Property Rights of Indigenous Peoples. The *Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples* that was endorsed by the participants includes the following:

> We declare that Indigenous Peoples of the world have the right to self determination: and in exercising that right must be recognized as the exclusive owners of their cultural and intellectual property.
>
> We recognize that Indigenous Peoples are capable of managing their traditional knowledge themselves, but

---

[38] P. Macklem, "Indigenous Rights and Multinational Corporations at International Law", 24 Hastings Int'l & Comp. L. Rev. 476, at 481.

[39] *Ibid.*, at 482.

[40] Discussed in: J. Arbour, "The Protection of Aboriginal Rights within a Human Rights Regime: In Search of an Analytical Framework for Section 25 of the Canadian Charter of Rights and Freedoms, (2001) 21 *Supreme Court Law Review* 3; P. Macklem, *Indigenous Difference and the Constitution of Canada*, 2001; G. Christie, "A Brief Discussion about Section 25 and Issues around Group Rights", unpublished, copy on file.

[41] Michael Davis, Social Policy Group, *Indigenous Peoples and Intellectual Property Rights*, Research Paper 20 1996-97, Parliament of Australia, Department of the Parliamentary Library, at 15, available at http://www.aph.gov.au/library/pubs/rp/1996-97/97rp20.htm, last viewed on March 17, 2004.

> are willing to offer it to all humanity provided their fundamental rights to define and control this knowledge are protected by the international community.[42]

Other statements in the document address the relationship to land and resources, as well as other cultural matters.

Reflecting the close relationship between lands and TK, the following statement is contained in the *Kimberley Declaration*, issued by the International Indigenous Peoples Summit on Sustainable Development, which took place in South Africa at the same time as the World Summit on Sustainable Development in August 2002:

> As peoples, we reaffirm our rights to self-determination and to own, control and manage our ancestral lands and territories, waters and other resources. Our lands and territories are at the core of our existence… they are inextricably linked to our survival and preservation and further development of our knowledge systems…[43]

A third example of a statement about indigenous concerns in relation to TK comes from an organization called Llamado de la Terra/Call of the Earth, an indigenous peoples' initiative on intellectual property policy, which held a workshop in November 2003 in Como, Italy to prepare for the third session of the Convention on Biological Diversity Working Group on Access and Benefit Sharing, held in December of the same year. In a deck presented during the working group session by representatives who attended the workshop, two principles of interest were identified:

> We hold sovereign rights over our knowledge, biological diversity and its components. Our knowledge is intrinsically linked to our biological diversity and therefore our knowledge is inalienable from our biological diversity.[44]

In addition, regarding the possible elaboration and negotiation by the Parties to the CBD of an international regime on access and benefit sharing with respect to genetic resources and associated traditional knowledge, Call of the Earth states that such a regime "must ensure that the right to prior informed consent of indigenous peoples is guaranteed and protected, as a fundamental principle in the exercise of self-determination and sovereignty of indigenous peoples".[45]

Although these statements represent only a narrow sample of those made internationally by indigenous people who are active in debate about TK, they are reflective of the core assertion that is widely made: *indigenous peoples have the right to own and control access to, and the use of, traditional knowledge*. Those who make this assertion do not necessarily draw a distinction between traditional knowledge that has not yet been disclosed and that which is in the public domain. The statement by Call of the Earth that indigenous people have sovereign rights over their traditional knowledge suggests that the distinction is irrelevant to them – whether information is public or not, indigenous people want to control how it is used, and, if they consent to its use by third parties, receive monetary or non-monetary benefits, as the case may be, in return.

As noted above, the assertion of rights to knowledge that is publicly available poses difficulties as this could have a significant impact on the biotechnology industry, on governments and on society, given that many advances in biotechnology have been based on knowledge about plants and other organisms that has long been in the public domain.[46]

7.4.2 The International Level

A. The International Biotechnology, Rights and TK Context

The WIPO Secretariat notes that "TK arises as an issue in relation to food and agriculture, biological diversity and the environment, biotechnology innovation and regulation, human rights, cultural policies and trade and economic development."[47] A number of international organizations address TK, albeit often described according to the particular lexicon in use in each fora. For example, the UNESCO General Conference adopted the *Universal Declaration on Cultural Diversity* in November 2001, which links the protection of traditional knowledge with human rights;[48] the World Health Organization is undertaking work on traditional medicines;[49] and the *International Treaty on Plant Genetic Resources,* which was negotiated under the auspices of the Food and Agriculture Organization, and will come into force following its ratification by forty States, addresses issues of interest to traditional farmers, including indigenous traditional farmers.[50]

---

[42] *The Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples*, adopted in June 1993 by the over 150 delegates that attended the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, held in Aotearoa, New Zealand, available at http://users.ox.ac.uk/~wgtrr/mataatua.htm, last viewed on March 17, 2004.

[43] *The Kimberley Declaration*, adopted by the Indigenous Peoples Summit on Sustainable Development at Kimberley, South Africa, August 23, 2002. Available at http://www.yachaywasi-ngo.org/kimberley.htm, last viewed on March 17, 2004.

[44] Llamado De La Terra/Call of the Earth, "Outcomes of the International Indigenous Workshop on Indigenous Perspectives on an International Regime on Access and Benefit Sharing to Traditional Knowledge and Associated Genetic Resources", held in Como on November 22–24, 2003, presented in Montreal on December 2, 2003, at 4. Copy on file.

[45] *Ibid.*, at 6.

[46] BIO letter, *supra* note 30.

Although developments in each of these fora are relevant to the issue of "TK rights", international negotiation respecting the relationship between traditional knowledge and biotechnology is primarily playing out in three international venues: the *Convention on Biological Diversity* (the CBD), WIPO and TRIPs Council.[51] The debate in these venues is arguably dominated by a focus on the economic interests of competing power blocs led by a number of States.[52]

That part of the biotechnology industry that is interested in access to genetic resources and protection of its intellectual property is primarily found in the United States, Japan and the European Community, which generally favour a situation in which intellectual property laws are similar across jurisdictions through broad adherence to TRIPs and to other international agreements relevant to the regulation of intellectual property.[53] Opposing them "are rapidly industrializing countries such as Brazil and India, which have emerging bioscience industries of their own as well as vast untapped reservoirs of biodiversity and Indigenous knowledge in their internally-colonized hinterlands."[54] These industrializing countries support efforts to recognize the intellectual property rights of indigenous peoples, possibly through novel measures, in order to reduce the ease with which researchers can access traditional knowledge without the provision of benefits. However, they do not necessarily support the flow of benefits derived from the application of traditional knowledge directly to indigenous communities. Rather, domestic legal systems might be used to ensure that traditional knowledge is treated as a national resource rather than as a resource of the indigenous peoples that hold it.[55]

An assessment of the rights implications of the international biotechnology debate is therefore a pressing concern. In fact, a narrow focus on economic interests appears to be giving way to a concern about the interests and rights of indigenous peoples related to biotechnology driven issues. In this environment, indigenous groups are having more success than they had in the past in giving voice to their concerns about the utilization of their TK. As is discussed in more detail below, both the Parties to the *Convention on Biological Diversity* (CBD) and the members of the World Intellectual Property Organization have created space for indigenous participation. As a result, references to, if not the elaboration of, indigenous rights related to traditional knowledge, have progressively increased in the various decisions adopted by the Parties to the CBD and in documents prepared by the

---

[47] WIPO document, *supra* note 14, at 6.

[48] Available at http://www.unesco.org/culture/pluralism/diversity/html_eng/decl_en.shtml, last viewed on March 30, 2004. The September 2003 General Conference of UNESCO adopted the *Convention on Intangible Cultural Heritage*, which is also relevant to traditional knowledge issues. That Convention is now available for ratification by the members of UNESCO. Canada has not ratified it due to concerns about the approach it takes to intangible cultural heritage.

[49] For information about the activities of WHO, see http://www.who.int/health_topics/traditional_medicine/en/, last viewed March 30, 2004.

[50] Available at: http://www.fao.org/ag/cgrfa/itpgr.htm, last viewed March 30, 2004.

[51] "TRIPs" is the *Agreement on Trade-Related Aspects of Intellectual Property Rights*, one of the family of agreements regulating international trade among the members of the World Trade Organization (WTO), all of whom are also party to TRIPs. It is the most comprehensive multilateral agreement on intellectual property rights. TRIPs Council is the body established under TRIPs to monitor the operation of the agreement and governments' compliance with it.

[52] The *Convention on Biological Diversity* is focused on the conservation of biological diversity. Nevertheless, economic considerations about the relationship between conservation and the financial benefits to be gained by certain States through the regulation of access to genetic resources is a dominant theme.

[53] Some States, notably the United States, have been seeking stronger protections for intellectual property rights in their bilateral and multilateral negotiations than those found in TRIPs.

[54] Barsh, *supra* note 17, at 13.

[55] *Ibid.*, at 14. This is not necessarily contrary to the provisions of the CBD, which reiterates State sovereignty over resources. Article 3 provides that States have "… the sovereign right to exploit their own resources pursuant to their own environmental policies…" Similarly, Article 15 begins with the words, "Recognizing the sovereign rights of States over their natural resources,…" Indigenous groups might argue that the CBD does not include any statement indicating that indigenous ownership and control of traditional knowledge is replaced by that of States.

WIPO Secretariat for the edification of the international community.[56] Meanwhile, the members of the World Trade Organization (WTO) have agreed to consider the relationship between TK and TRIPs as part of the trade and development agenda adopted at the ministerial session held in Doha in 2002.[57]

B. Indigenous Rights at International Law

The international legal system is based on the premise that States are sovereign entities that are the sole subjects of international law. Early in the 20th century the international system was described by reference to billiard ball States crashing one into the other.[58] The domestic treatment of the contents of each billiard ball was regarded as a matter of sovereignty of little interest to the international community. Beginning after World War II, this vision of the international system, perhaps never very accurate, has progressively accommodated a shift in favour of consideration of the rights of individuals and peoples and the responsibilities of those who govern them.

Over the course of twenty years or so, indigenous people have emerged as one of the most important "non-State" actors in the international theatre. Today, representatives of indigenous groups are more frequently able to express their concerns in various international fora alongside representatives of States, international organizations more frequently integrate consideration of indigenous issues in their work and activities, and States more frequently experience recriminations internationally for discrimination against indigenous groups living within their borders.

On the basis of a number of developments in the last twenty years, indigenous groups have managed to influence the international system in a number of profound ways. These developments include: (1) the increased use by indigenous groups of international human rights complaints mechanisms; (2) the on-going negotiations towards declarations on indigenous rights at the OAS[59] and UN; (3) the ever-increasing attention being paid to indigenous issues by a variety of international organizations such as the CBD, WIPO, the World Bank, UNCTAD[60] and others; and (4) the efforts by the members of the UN to integrate the consideration of indigenous issues in all relevant international activities in which they participate via in particular the establishment of the UN Permanent Forum on Indigenous Issues.[61]

Despite the considerable success that indigenous people have had in making their voices heard at the international level, a widely accepted elaboration of their rights at international law has not yet occurred. Instead, indigenous rights are addressed piecemeal in various instruments, by various treaty bodies and through various processes. The lack of a widely accepted elaboration – a declaration endorsed by the members of the United Nations or a widely ratified international convention, for example – does not mean that international norms respecting international indigenous rights are not evolving. Indeed, some commentators argue that such norms have already emerged and are part of customary international law – that body of international law derived from shared State practice undertaken based on the widely accepted view that such practice is governed by internationally recognized rules.[62]

---

[56] This is discussed in more detail below.

[57] The November 14, 2001 Ministerial Declaration of the members of the WTO (the Doha Declaration) includes the following work item for the TRIPS Council: "19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the *Convention on Biological Diversity*, the protection of traditional knowledge and folklore, and other relevant new developments raised by members ..." There has been very little progress on this work so far.

[58] The "billiard ball" analogy is attributed to Oppenheim and is discussed by B. Kingsbury in "Sovereignty and Inequality", 9(4) Eur. J. of Int'l L., available at http://www.ejil.org/journal/Vol9/No4/art1-01.html, last viewed on October 8, 2003. Kingsbury notes that the orthodox view throughout most of the 20th century was that the "... division of the world into functionally and juridically similar territorial units implied that, provided the entity was treated internationally as a state, its domestic structure and regime type did not matter."

[59] "OAS" refers to the Organization of American States.

[60] "UNCTAD" refers to the United Nations Committee on Trade and Development.

[61] The UN Permanent Forum on Indigenous Issues was established by the UN Economic and Social Council (ECOSOC) in accordance with its resolution E/RES/2000/22 as a subsidiary organ of the Council. The Forum consists of 16 members, 8 of which are appointed by governments and elected by the Council and 8 of which are appointed by the President of the Council, following broad consultations with Indigenous organizations. The Forum acts as an advisory body to the Council with a broad mandate to consider and report on Indigenous issues. For more information, see the Forum website: http://www.un.org/esa/socdev/pfii.

[62] See Kingsbury, "Operational Policies of International Institutions as Part of the Law-Making Process: The World Bank and Indigenous Peoples", *The Reality of International Law: Essays in Honour of Ian Brownlie*, 1999.

Such a conception of customary international law is easier to hold for those who have a flexible view of what constitutes State practice in the early part of the new century. Benedict Kingsbury, for example, has described World Bank operational policies that make Bank funding conditional on a State's treatment of its domestic indigenous population as a non-traditional candidate for designation as a source of "customary international indigenous law".[63] He states that "the iteration, elaboration, and application of norms involves interactions and dialogues among public international institutions, national law and policy, indigenous peoples, NGOs, market actors, the academy, and others."[64] If Kingsbury is correct, the elaboration of international indigenous rights is indeed active as more and more international and national players participate in dialogue about indigenous issues. On the other hand, Kingsbury's attention to non-traditional candidates for international norm creation may reflect a lack of less contentious evidence of State practice and *opinio juris* respecting customary international law on indigenous rights.

James Anaya argues that indigenous peoples have used the international system to more radically alter the State sovereignty norm than that brought about by the internationalization of individual human rights. In Anaya's view, indigenous claims to group autonomy and collective rights of control over lands and resources challenge the primacy of the State more fundamentally than do the assertions of classical human rights theory. Further, indigenous groups have used international human rights to shift policies addressing indigenous peoples from a focus on assimilation to one based on respect, and have gained recognition as having a unique status that merits their enhanced participation in international processes.[65]

For Anaya, customary international norms respecting indigenous rights have already emerged in binding form. This view tends towards one end of a spectrum, and may not s be shared by many States. However, States cannot deny, in the words of Bob Dylan, that "something is happening", even if they "don't know what it is"[66] in relation to the process of international norm creation respecting indigenous rights.

C. Are There Rights to Traditional Knowledge at International Law?

"Rights" in relation to traditional knowledge have not been formulated internationally in a treaty or other widely accepted instrument. The key international instrument addressing traditional knowledge is the *Convention on Biological Diversity* (CBD). Although it is not a human rights instrument, the CBD does set out obligations for States Parties, including Canada. Accordingly, subsection (i) below addresses the CBD and a related forum, the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC). "Rights talk" is more and more common at both fora in relation to indigenous peoples and traditional knowledge. Subsection (ii) therefore addresses whether there is a basis in international human and indigenous rights instruments to ground assertions respecting the existence of an indigenous right to own and control traditional knowledge.

(i) Traditional Knowledge, Biological Diversity and Intellectual Property

The CBD

Traditional knowledge was first given some prominence internationally in connection with the topic of sustainable development. At the 1992 United Nations Conference on the Environment and Development in Rio de Janeiro, at which Canada played a leading role, a number of instruments were elaborated that include consideration of TK issues.[67] The most important of these is the *Convention on Biological Diversity*, which was signed by most of the

---

[63] Kingsbury, "Reconciling Five Competing Conceptual Structures of Indigenous Peoples' Claims in International and Comparative Law", *People's Rights*, 2001, at 340.

[64] Kingsbury, 1999, supra note 62 at 327 to 328.

[65] J. Anaya, "Indigenous Peoples and International Law Issues, (1998) 92 Am. Soc'y Int'l L. Proc. 96, at 96 to 98.

[66] B. Dylan, *Ballad of a Thin Man*, Copyright 1965.

[67] Besides the CBD, the *Rio Declaration on the Environment and Development* and *Agenda 21*, a comprehensive plan of action for the world with respect to sustainable development address TK. Principle 22 of the Rio Declaration proclaims that: "Indigenous people and their communities and other local communities have a vital role in environmental management and development because of their knowledge and traditional practices. States recognize and duly support their identity, culture and interests and enable their effective participation in the achievement of sustainable development." Chapter 26 of Agenda 21 is entitled "Recognizing and Strengthening the Role of Indigenous People and their Communities." It includes the following objective, which governments "should aim at fulfilling," "in full partnership with indigenous people and their communities," "where appropriate": "26.3(a) Establishment of a process to empower indigenous people and their communities through measures that include: (iii) Recognition of their values, traditional knowledge and resource management practices with a view to promoting environmentally sound and sustainable development." The full texts of the Rio Declaration and of Agenda 21 are available at http://www.un.org/esa/sustdev/documents, last visited on March 22, 2004.

178 governments that attended the Rio Conference. Today the CBD is one of the most widely ratified international treaties currently in force.[68] It includes three main objectives: (1) the conservation of biological diversity; (2) the sustainable use of its components; and (3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.[69]

The CBD recognizes the unique contribution indigenous people and their traditional knowledge make to sustainable development. First, in the preamble to the Convention the Parties recognize "the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components." Article 10(c) states that each Contracting Party shall, "as far as possible and as appropriate", "[p]rotect and encourage customary use of biological resources in accordance with traditional cultural practices..."[70] Most importantly, from the perspective of indigenous groups interested in the protection of their traditional knowledge, the CBD includes the only reference to traditional knowledge currently to be found in any binding international treaty. Article 8j provides:

> Each Contracting Party shall, as far as possible and as appropriate
>
> j. Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.[71]

Although it is qualified by the words "as far as possible and as appropriate" and by reference to national legislation, Article 8j establishes important State obligations respecting the utilization of traditional knowledge: (1) TK should be respected, preserved and maintained; (2) the approval and involvement of traditional knowledge holders should be sought in the promotion of the wider application of TK; and (3) the equitable sharing of the benefits arising from the utilization of TK should be encouraged.

The obligations set out in Article 8j are reinforced by steps that have been taken by the Parties to the CBD in furtherance of the implementation of its provisions. First, the Conference of the Parties (COP) of the CBD meet every two years when they negotiate, consider and adopt pages of resolutions in decisions aimed at progressive implementation of the commitments they took on when they ratified the Convention.[72] References to traditional knowledge, and, of more interest from the perspective of this chapter, to the need to "respect the rights of indigenous and local communities", to the notion of prior informed consent with respect to access to traditional knowledge, and other themes of interest to indigenous groups, have increased over time in COP decisions.[73]

Second, in 1998, the COP established the Working Group on Article 8j and Related Provisions (WG8J), with a mandate to provide advice to the COP on the development of legal and other forms of protection for TK and respecting the implementation of Article 8j, to develop a programme of work on the topic, to recommend priorities and to provide advice on measures to strengthen cooperation at the international level among indigenous and local communities on TK issues.[74] In addition to providing a venue for discussion about traditional knowledge and its relationship to the conservation of biological diversity, WG8J has permitted extensive indigenous participation alongside States in negotiations and debate respecting Article 8j, although States retain ultimate decision making authority.

---

[68] There are 188 Parties to the CBD. Canada ratified the Convention on April 12, 1992. A noteworthy non-Party is the United States, which has signed the Convention, but not ratified it. A list of Parties is available at the CBD website: http://www.biodiv.org.

[69] CBD, *supra* note 9, Article 1.

[70] *Ibid.*, Article 10(c).

[71] *Ibid*, Article 8j. Other articles of particular interest in relation to traditional knowledge include Article 15, which addresses genetic resources, Article 16 on transfer of technology and Article 22 on the relationship between the CBD and other international conventions.

[72] The Conference of the Parties (COP) was established pursuant to Article 23 of the CBD. Its mandate is to "keep under review the implementation of" the Convention. It considers amendments to the Convention, establishes and amends protocols, establishes subsidiary bodies to address specific issues, among other things. It therefore generally carries out a legislative or normative function. The administrative functions of the CBD are carried out by a Secretariat, established by Article 24, and located in Montreal.

[73] See generally, the COP decisions on Article 8j and on genetic resources. Decisions on protected areas, tourism, and mountain biological diversity are also of interest. COP decisions are available at the CBD website: http://www.biodiv.org, last viewed March 29, 2004.

Participation in WG8J has allowed indigenous groups to articulate their views and to place their concerns about rights and TK on the agenda. Indigenous groups also seek a heightened level of participation in another important venue established by the COP, the Working Group on Access and Benefit Sharing (WGABS).[75] Based on WGABS recommendations, a decision initiating the negotiation and elaboration of an international access and benefit sharing regime with respect to genetic resources was adopted by the COP at its seventh session in February 2004. A paragraph of the relevant COP decision calls for increased indigenous participation in that process.[76]

Besides establishing a framework of obligations related to TK, at least for the States that have ratified it, the CBD, and the process that States are engaged in through the biannual COP meetings, and regular working group sessions on various matters, has helped in the identification of key issues respecting TK, albeit not necessarily in terms of formal obligations. Article 8j and related provisions of the CBD, together with various COP decisions, and WG8J and WGABS recommendations suggest, as indicated at the beginning of this chapter, that TK is not just about knowledge, it is about the relationship, often described in the language of rights, between indigenous people and land, culture and control over matters integral to their communities, including control over decisions whether to seek economic reward by marketing their assets.

The progressive identification of relevant TK issues and the elaboration of means to implement Article 8j by the Parties to the CBD, together with the active participation of indigenous representatives, give additional focus to relevant State obligations in the CBD. Although COP decisions are not binding, they are relevant to norm creation or elaboration in the context of the CBD.

The WIPO IGC

In 2000, the members of WIPO established the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (the IGC) as an international forum for debate and discussion about the interplay between intellectual property and genetic resources, traditional knowledge and folklore.[77] Although they are independent of each other, on the basis of direction received from the members of WIPO and the Parties to the CBD, who are not all the same, the IGC and the CBD COP and WG8J are engaged in something of a pained dialogue about traditional knowledge issues. The CBD process is regarded as leading on questions about the relationship between TK and the conservation of biological diversity, while WIPO, via the IGC in large part, leads on questions about the relationship between TK and intellectual property rights. In fact the situation is more complex. Nevertheless, it is helpful to mention the WIPO IGC here.

The IGC finds itself in the middle of the divide that separates States representing the major power blocs in global intellectual property issues. Developed countries with large biotechnology industries are not all convinced that the intellectual property system requires significant alteration to accommodate intellectual property rights in TK. Developing countries believe the status quo is not effective. Certain modifications to the intellectual property system have been proposed such as voluntary or mandatory disclosure requirements whereby patent applicants would have to indicate whether TK was used in developing the product, and whether genetic resources were collected and where. Adding to the complexity, countries representing in particular the megadiverse developing world ultimately seek modifications to TRIPs, which is the key standard bearer respecting the global intellectual property rights regime.[78]

---

[74] CBD, COP Decision IV/9, available at http://www.biodiv.org, last viewed on March 29, 2004.

[75] The Working Group on Access and Benefit Sharing was established by the COP at its fifth meeting, held in 1998, to develop guidelines and other approaches to address access to genetic resources and benefit-sharing, the topics covered by Article 15 of the CBD. See CBD, COP Decision V/26, available at http://www.biodiv.org, last viewed on March 29, 2004. Based on a recommendation from the WGABS, the COP adopted the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* at its sixth meeting in 2000. See COP Decision VI/24, available at http://www.biodiv.org, last viewed March 29, 2004.

[76] The final decisions from the seventh meeting of the COP, held in February 2004 are not yet available on the CBD website, but will eventually be accessible there. The final draft decision respecting access and benefit sharing, document UNEP/CBD/COP/7/L.28, can be found at http://www.biodiv.org, last viewed April 1, 2004. See in particular item D, beginning on page 3 of the document ("international regime on access to genetic resources and benefit sharing").

[77] For information about the IGC, visit the WIPO website at http://www.wipo.org. The initial mandate is contained in WIPO document: WO/GA/26/6, para. 14.

The IGC amounts to a compromise of sorts – it was established to examine these issues, but not to create a venue for the negotiation of an intellectual property or *sui generis* regime to protect TK, at least not yet. Based partly on Member State contributions, the WIPO Secretariat has produced useful documents on the subject of TK, which may have some impact on the level of understanding internationally about the relationship between TK and the intellectual property system. However, many developing countries feel that its research reports, albeit well crafted and thoughtful, do not amount to much. These countries are anxious for accelerated movement towards the development of an international regime addressing traditional knowledge.[79]

At this point, the CBD and WIPO fora are each significant in relation to TK and rights. Canada is an active participant in both venues in discussions about TK and related issues of importance to indigenous people, and supports indigenous participation therein. Although neither the CBD nor the WIPO IGC is an indigenous rights elaborating venue, "rights talk" is increasingly prevalent in both, and principles that are important to indigenous people, such as prior informed consent with respect to access to TK, are being discussed and elaborated. References to rights in CBD and WIPO documents, however, are made without an analysis of possible sources for them in international human rights law, which is the focus of the following subsection. Since it is possible that States will decide that an international *sui generis* regime addressing traditional knowledge and its relationship to intellectual property law needs to be elaborated, such an analysis is wanting.

(ii) International Rights Instruments

Arguments in favour of the proposition that indigenous peoples have a right to own and control traditional knowledge would likely draw on a number of sources. This subsection addresses those that are likely to be the most important in this regard: international instruments addressing indigenous rights specifically, and those addressing human rights generally that are sometimes applied to the specific circumstances of indigenous peoples. Neither international nor Canadian judicial bodies have addressed TK rights under international law specifically. Nevertheless, some guidance may be drawn from these sources.

International Instruments Addressing Indigenous Rights Specifically

ILO Convention 169

International Labour Organization (ILO) *Convention (No. 169) concerning Indigenous and Tribal Peoples in Independent Countries*, adopted by the General Conference of the ILO on June 27, 1989, is currently the only multilateral treaty in force focusing exclusively on the rights of indigenous peoples.[80] Although ILO 169 is an important source of obligations for the 17 countries that have ratified it, and is referred to from time to time in international documents, it has not been ratified by very many countries, including a number of those that are particularly active in international discussions about indigenous rights such as Canada, the United States and Australia. In addition, the Convention neither addresses the right of indigenous peoples to self-determination, nor the subject of traditional knowledge, as it was adopted before TK became an issue on the international agenda. However, it does contain relevant provisions, including Article 7(1), which states:

> The peoples concerned shall have the right to decide their own priorities for the process of development as it affects their lives, beliefs, institutions and spiritual well-being and the lands they occupy or otherwise use, and to exercise control, to the extent possible, over their own economic, social and cultural development.[81]

---

[78] For a recent update on debates about the relationship between the CBD, WIPO and TRIPS, see Volume 4, Number 5 of *Bridges Trade BioRes*, available at: http://www.ictsd.org/biores/04-03-19/story2.htm, last viewed March 30, 2004.

[79] A new "accelerated" mandate for the WIPO IGC was adopted by the WIPO General Assembly in September 2003. The African Group submitted a proposal to the sixth IGC session, held in March 2004, that it feels would be in keeping with this mandate, available at http://www.wipo.int/documents/en/meetings/2004/igc/pdf/grtkf_ic_6_12.pdf, last viewed March 30, 2004.

[80] Came into force September 5, 1991.

[81] ILO Convention 169 is available at http://www.unhchr.ch/html/menu3/b/62.htm, last viewed March 31, 2004.

Although its treatment here is brief, it should be noted that it has been argued that ILO Convention 169 reflects emergent customary international law[82] and could therefore arise in cases addressing international indigenous rights to TK.

Draft Declarations on Indigenous Rights

Other than ILO Convention 169, international instruments specifically addressing indigenous rights are either non-binding[83] or in draft form only. Of these instruments, the most important are the two separate draft declarations on indigenous rights currently being discussed at intergovernmental working groups under the auspices of the UN and the OAS.[84] If they are ever adopted, these declarations will occupy a central position in the articulation of international indigenous rights, although they too would be hortatory and non-binding instruments. However, even in their current form, the draft declarations have been referred to as sources of relevant principles of international law,[85] including by the Supreme Court of Canada.[86] Accordingly their significance to questions about the existence of international indigenous rights respecting traditional knowledge should not be ignored regardless of their current status.

Discussions at both the OAS and UN working groups on the draft declarations are addressing a number of contentious and challenging issues, such as the right of indigenous peoples to self-determination, the nature and scope of any collective rights, and the elaboration, in a thorough manner, of indigenous rights to land and resources. Both working groups are conducting their negotiations on the basis of draft texts prepared by experts. Although there are important differences between them, including the fact that indigenous representatives have been granted a greater degree of participation in the UN working group than in that operating at the OAS, for the most part the rights described in the two draft texts are similar. Since the two processes are fairly similar, the following discussion focuses on the UN *Draft Declaration on the Rights of Indigenous Peoples* (the draft Declaration). Canada is an active participant in both processes, and encourages the participation of indigenous people in them.

In 1993, the UN Working Group on Indigenous Populations (WGIP), a working group of five experts, completed a ten year process of drafting a declaration on the rights of indigenous peoples, during which time they took into account input from States and indigenous people.

In 1995, a working group of states (the *ad hoc* open ended Working Group on the Draft Declaration (WGDD)) was established by the UN Commission on Human Rights, and given the responsibility to elaborate a Declaration for adoption by the UN General Assembly. The CHR also committed in that resolution to adopt a Declaration by the end of the International Decade of the World's Indigenous People (1994-2004). At its first meeting, the WGDD agreed to use the draft Declaration prepared by the experts as the basis for its work.

---

[82] In submissions he made to the Royal Commission on Aboriginal Peoples in 1995, James Anaya wrote that the Convention "represents a core of expectations that are widely shared internationally and, accordingly, it reflects emergent customary international law generally binding upon the constituent units of the international community." J. Anaya, "Canada's Fiduciary Obligations Towards Indigenous Peoples in Quebec Under International Law", in Royal Commission on Aboriginal Peoples, *Canada's Fiduciary Obligations to Aboriginal Peoples in the Context of Accession to Sovereignty by Quebec, Volume 1: International Dimensions*, 1995, at 20. Given its small number of Parties, Anaya's statement seems to exaggerate the Convention's international customary law making importance.

[83] For example, the UN General Assembly and UN Human Rights Commission have adopted resolutions respecting indigenous issues annually for a number of years. These declarations are non-binding hortatory statements. Some argue that they do have an effect on the generation of international norms over time, particularly where accompanied by other evidence that they reflect generally accepted principles of law.

[84] The UN *Draft Declaration on the Rights of Indigenous Peoples* is included in document E/CN.4/sub.2/1994/2/Add.1 (1994). It is available at http://www1.umn.edu/humanrts/instree/declra.htm, last viewed March 31, 2004. The *Proposed American Declaration on the Rights of Indigenous Peoples* was approved by the Inter-American Commission on Human Rights on February 26, 1997. This is the text that has been the basis for negotiations since then. The Chair of the Working Group to Prepare the Proposed American Declaration on the Rights of Indigenous Peoples has prepared a consolidated text that includes proposed revisions, dated June 2003. The consolidated text is available at http://www.dialoguebetweennations.com/OASdeclaration/english/ConsolidatedTextofDD.htm, last viewed March 31, 2004.

[85] See Inter-American Commission on Human Rights, *Mary and Carrie Dann v. United States*, Report 75/02, December 27, 2002, paras. 128 to 130; Inter-American Commission, *Maya Indigenous Communities of the Toledo District v. Belize*, Report 96/03, October 24, 2003; and Inter-American Court of Human Rights, *The Case of the Mayagna (Sumo) Awas Tingni Community v Nicaragua*, Judgment of August 31, 2001 (Ser. C) No. 79 (2001), Concurring Opinion of Judge Sergio Garcia Ramirez. In contrast, Russel Barsh notes that the declarations, if adopted, would only be largely advisory in nature, and that declarations of UN bodies are rarely regarded as sources of law by domestic courts. (Barsh, *supra* note 17, at 11 and 12.)

[86] The UN and OAS draft Declarations and ILO Convention 169 are referred to by the Court in *Mitchell v. M.N.R.* [2001] 1 S.C.R. 911.

With the end of the decade approaching, pressure has increased within the WGDD to achieve a declaration that can be forwarded through the UN for adoption by the General Assembly. Given that only a couple of the articles in the draft have been provisionally adopted to date, and the number of different positions that have been tabled by States during recent sessions,[87] it would be surprising if consensus on the document emerges before the end of 2004, the target date for adoption. It is more likely that the mandate of the WGDD will have to be extended in order to complete the process.

The draft Declaration includes a provision addressing traditional knowledge. Article 29 provides:

> Indigenous Peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property.
>
> They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seed, medicines, knowledge of the properties of fauna and flora, oral traditional, literatures, designs and visual and performing arts.[88]

In 1994, the Secretariat of the Commission on Human Rights produced a technical study on the draft Declaration with the objective of explaining the genesis of and relationship between certain articles, with recommendations to States for revisions to the text to reduce duplication and increase clarity. The study does not offer much insight about the foundation for draft Article 29, noting the existence of Article 8j in the CBD. Also mentioned is work that was then underway by the Special Rapporteur on Indigenous Cultural Heritage respecting the development of guidelines on that topic.[89] Since then, the *Principles and Guidelines for the Protection of the Heritage of Indigenous People* have been elaborated by the Special Rapporteur. The Guidelines have not been adopted by the members of the UN and are not binding, but do reflect the approach taken in Article 29 of the draft Declaration, including the following:

> To be effective, the protection of indigenous peoples' heritage should be based broadly on the principle of self-determination, which includes the right of indigenous peoples to maintain and develop their own cultures and knowledge systems, and forms of social organization.[90]

Although draft Article 29 and the Guidelines do speak to the claims asserted and objectives to be inferred from the indigenous peoples' statements outlined above, the declaration remains in draft form, and the guidelines on indigenous cultural heritage are not binding. It is not yet certain whether States will resolve concerns that were expressed by some participants in informal intersessional consultations held prior to the 2002 meeting of the WGDD about the relationship between the principles addressed in draft Article 29 and intellectual property laws.[91]

Generally, progress at the WGDD has been very slow. Some indigenous representatives insist that the declaration must be submitted to the General Assembly and adopted as is. Most States that are active in the process, however, seek changes to some or all of the draft articles.[92] Although it would not be a binding treaty, a UN declaration on the rights of indigenous peoples would be used widely by indigenous groups and their supporters (including States in some cases) to advance their interests, by international treaty bodies and others to interpret and define international indigenous rights, and by domestic courts to inform their interpretations of relevant domestic law.[93] The OAS process towards the adoption of a declaration on indigenous rights is following a similar timeline, and will also likely be widely used if it is ever adopted, although it will have a hemispheric rather than global focus.

---

[87] See, for example, the last two reports of the Chairperson-Rapporteur of the Working Group: E/CN.4/2003/92 and E/CN.4/2004/81.

[88] UN draft Declaration, *supra* note 84. The June 2003 Chair's consolidated text of the *Proposed American Declaration on the Rights of Indigenous Peoples* includes the following provisions respecting traditional knowledge and intellectual property: "1. Indigenous peoples have the right to the recognition of the property, control, development, and protection of their cultural patrimony through special regimes that recognizes the communal nature of said property. Such regimes shall be established with their informed consent and participation. 2. Indigenous peoples also have the right to the legal protection of that property through patents, commercial trademarks, copyright, and other general procedures of intellectual property. 3. The patrimony of indigenous peoples includes, *inter alia*, the knowledge, ancestral designs and procedures, artistic, spiritual, technological, scientific, and biogenetic expressions, as well as the knowledge and developments of their own related to the utility and qualities of medicinal plants." *Supra* note 84.

[89] UN Commission on Human Rights, *Technical review of the United Nations draft declaration on the rights of indigenous peoples*, Note by the secretariat, E/CN.4/Sub.2/1994/2, paras. 49 to 51 and 97. Of some interest, the study does not link Article 29 of the draft Declaration with Article 15 of the ICESCR, which is discussed below.

[90] The text of the *Draft principles and guidelines for the protection of the heritage of indigenous people* is included in Annex 1 to E/CN.4/sub.2/2000/26.

[91] The views expressed are summarized in the Summary of the Informal Intersessional Consultations: Geneva 16 to 19 September 2002, available at http://www.treatycouncil.org/new_page_552.htm, last viewed March 31, 2004.

[92] *Supra* note 87.

International Human Rights Instruments Generally

ICESCR and ICCPR

Canada has ratified the two core international instruments that define international human rights – the *International Covenant on Civil and Political Rights* (ICCPR) and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR). Articles that are relevant to TK issues are found in both Covenants. None of these articles address an indigenous right to own and control traditional knowledge, or any other indigenous right for that matter, in specific terms. However, they are binding instruments with respect to the States that have ratified them and set out universal human rights that can be applied to the circumstances of indigenous peoples.

One possible source of human rights relevant to the question whether indigenous groups are entitled to the protection of their traditional knowledge is found in Article 15 of the ICESCR. Of the provisions that are found in the two Covenants, this article is regarded as the most clearly relevant to intellectual property rights and to cultural matters.[94] The relationship between human rights and intellectual property rights has received little attention internationally until recently. Intellectual property rights have generally been viewed as matters of economic interest. This understanding has been challenged most deeply by the HIV/AIDS crisis in some regions of the world, particularly sub-Saharan Africa, and the links that were made between that crisis and certain restrictions on access to HIV treatments.[95] Traditional knowledge is a second issue driving debate about this topic, although so far in the shadows of the former.

Article 15 provides as follows:

> 1. The States Parties of the present Covenant recognize the right of everyone:
>   a. To take part in cultural life;
>   b. To enjoy the benefits of scientific progress and its applications;
>   c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
> 2. The steps to be taken by the States Parties to the present Covenant to achieve full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
> 4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.[96]

In a report prepared for the 24th session of the Committee on Economic, Social and Cultural Rights (CESCR), three human rights considerations relevant to intellectual property and to the interpretation of Article 15 are identified: (1) the central role played by intellectual property rights in the world economy underscores the need for human rights advocates to claim the rights of the author, creator and inventor, whether an individual, a group, or a community, as a human right; (2) the rights of everyone in the global community to secure access to knowledge is equally important; and (3) whether existing intellectual property laws are consistent with human dignity and the realization of human rights.[97]

---

[93] It is always possible that the declaration, if adopted, would become the basis for a future treaty on Indigenous rights, although the slow negotiation process to date would suggest that such a step will not be taken for some time.

[94] Article 15 of the ICESCR is an elaboration of Article 27 of the *Universal Declaration of Human Rights* (UDHR). A similar article is also found in the *American Declaration on the Rights and Duties of Man*.

[95] The chapter of this paper addressing patents contains a discussion of this issue.

[96] ICESCR, Article 15.

[97] A. Chapman, "Approaching Intellectual Property as a Human Rights: Obligations Related to Article 15(1)(c), discussion paper submitted to the Committee on Economic, Social and Cultural Rights, 24th session, E/C.12/2000/12, October 3, 2000, at para. 5.

Although these considerations are undoubtedly important, the value of Article 15 as a source of rights relevant to traditional knowledge may be limited. This is partly because it has not been the subject of much consideration, including by the CESCR, until recently.[98] Accordingly, little guidance is available regarding its interpretation or its application to traditional knowledge.

A lack of attention to Article 15 can be attributed in part to the lesser importance that has been placed on economic, social and cultural rights as compared to more concrete civil and political rights.[99] In addition, the lack of a mechanism for individuals or groups to bring complaints against States under the ICESCR may have reduced opportunities to elaborate the content of this Article.[100]

More importantly for the purposes of this chapter, Article 15 does not reflect indigenous views about traditional knowledge. The right described in the Article, like all of the rights in the ICESCR and ICCPR, with the exception of Common Article 1, the right to self-determination of peoples, is cast as a right of individuals. This vision of the rights described in the Covenants is not conducive to the view that traditional knowledge is collectively owned and controlled by indigenous communities. Further, although the international community has recognized the interrelatedness of all human rights,[101] the rights set out in the two Covenants are expressed in discrete terms. As indicated above, the assertion of a right to control TK is related to broader claims by indigenous peoples about collective land, cultural and self-determination rights that are not fully elaborated in the two Covenants.

In addition, the emphasis in Article 15 on sharing intellectual advances globally does not respond to the competing interest that indigenous people have in controlling access to traditional knowledge and, if it is consensually disclosed, how it is used. A desire among indigenous communities to maintain control over TK may not necessarily entail keeping it secret but it can mean that the interests of the community holding the knowledge may receive greater weight than the interests of others to use the knowledge that is protected. Article 15 does not itself provide sufficient guidance to resolve the balancing that may be required because it is based on a view that the competing interests are those of the individual creator versus those of society as a whole. By providing creators with an incentive to share their innovations in the form of monopoly property rights for a defined period of time, the intellectual property system arguably reflects the values expressed in Article 15, but falls short of considerations important to indigenous communities in relation to their traditional knowledge.

A second, and possibly more fruitful, source of rights relevant to TK is Article 27 of the ICCPR — the right of an individual to practice his or her culture in community with others. Article 27 provides:

> In those States in which ethnic, religious or linguistic minorities exist, persons belonging to such minorities shall not be denied the right, in community with the other members of their group, to enjoy their own culture, to profess and practice their own religion, or to use their own language.[102]

The Human Rights Committee has considered a number of complaints by indigenous individuals against the governments of the States in which they live, including Canada.[103] However, these have tended to relate to the participation by individuals in certain traditional activities or to benefit from programs or laws that are available to a select class of indigenous people living in the State concerned.[104] Complaints related specifically to traditional knowledge have not been made.

---

[98] *Ibid.*, at para. 25. This is changing. The CESCR has produced a draft General Comment on a subparagraph of Article 15 — Article 15(1)(c) — which it shared selectively with experts in August 2004 and considered during its 33rd session in November 2004. Under pressure from non-governmental organizations and others, the Committee did not adopt the draft pending further review.

[99] See A. Eide and A Rosas, "Economic, Social and Cultural Rights: A Universal Challenge", in *Economic, Social and Cultural Rights*, 2nd ed., 2001, ed. A Eide.

[100] This may change. A UN working group has been established to consider whether a complaints mechanism should be developed for the ICESCR, akin to the optional protocol to the ICCPR.

[101] See the *Vienna Declaration and Programme of Action*, adopted by the World Conference on Human Rights on June 25, 1993, for example.

[102] ICCPR, Article 27.

[103] A full list of the Human Rights Committee jurisprudence respecting complaints by indigenous people can be found at http://www.bayefsky.com, last viewed March 31, 2004.

Nevertheless, the Committee has developed some of its own relevant jurisprudence through its consideration of these complaints. Reflecting this, in its General Comment respecting Article 27, the Committee has shown a desire to accommodate aspects of indigenous rights claims related to cultural matters. For example, the Committee has suggested that positive legal measures may be required to ensure the enjoyment of the rights set out in the Article, and further that culture manifests itself in many forms, "including a particular way of life associated with the use of land resources, especially in the case of indigenous peoples."[105]

The Committee's general approach to indigenous complaints appears to embrace the notion that competing interests must be balanced by States, but with a view to rights based bottom lines. For example, the Committee has stated that:

> A State may understandably wish to encourage development or allow economic activity by enterprise. The scope of its freedom to do so is not to be assessed by reference to a margin of appreciation, but by reference to the obligations it has undertaken in Article 27. Article 27 requires that a member of a minority shall not be denied his right to enjoy his own culture. Thus, measures whose impact amount to a denial of the right will not be compatible with the obligations under Article 27. However, measures that have a certain limited impact on the way of life of persons belonging to a minority will not necessarily amount to a denial of the right under Article 27.[106]

In determining whether the right to enjoy one's culture is actually denied as opposed to impacted in a limited way, the Committee will consider whether the members of the minority in question were given opportunities to participate in the decision making process related to the measures that a complaint relates to, and whether the minority will continue to be able to benefit from its traditional economy.[107] Key principles identified by the Committee in relation to Article 27 include the following: (1) a balance of interests in the carrying out of government activities, with due regard to the core human rights obligation at stake, should be achieved; (2) affected indigenous groups should be involved in relevant decision making; and (3) affected indigenous groups should still be able to benefit from their traditional activities and economies after the government activity is undertaken. These principles could each be relevant to any complaints arising in relation to indigenous concerns about the impact of government activities on traditional knowledge.[108]

There are limits to the usefulness of Article 27 in relation to questions about traditional knowledge. First, the optional protocol to the ICCPR establishes a process for individual complaints, but does not do so for groups, in the view of the Human Rights Committee, thereby limiting its value for indigenous peoples.[109] In addition, the Committee has acknowledged that it is limited by the language of the individual rights it has been mandated to interpret. In clarifying that the right to self-determination in Article 1 of the ICCPR and the right protected under Article 27 are different, the Committee has stated that Article 27 is an individual right, not a right of peoples.[110] Finally, Article 27 describes a right to enjoy one's own culture in community with others. It does not describe a right of a community to own and control its cultural assets, which may include traditional knowledge thereby falling short of the claim made by indigenous groups regarding traditional knowledge.

Finally, it should be noted that the fact that Article 15 of the ICESCR and Article 27 of ICCPR are cast as individual rights means that they, and the other articles of the Covenants, may place limits on what steps can be taken by States and any indigenous governments (such as aboriginal governments operating pursuant to self-government agreements in Canada) to try to address indigenous claims that they have a collective right to control the utilization of their traditional knowledge. Particularly in the absence of a widely accepted iteration of the collective rights of indigenous groups internationally, the balancing that might be required between individual rights in the Covenants and asserted collective rights would favour individual rights since their status at international law is generally unquestioned.

---

[104] Examples include *Lovelace v. Canada* (24/1977)(R.6/24), ICCPR, A/36/40 (30 July 1981) 166, concerning the complainant's exclusion from "Indian status" under the *Indian Act*; *Kitok v. Sweden* (197/1985), ICCPR, A/43/40 (27 July 1988) 221, concerning the complainant's exclusion from Sami membership and thereby from reindeer herding privileges; and *Mahuika v. New Zealand* (547/1993), ICCPR, A/56/40 vol. II (27 October 2000) 11, concerning the regulation of Maori fishers.

[105] Human Rights Committee General Comment No. 23, adopted during the Committee's 50th session in 1994, para. 7. For a discussion, see S. Prichard and C. Heindow-Dolman, "Indigenous peoples and international law: A critical overview", (1998) 3 AILR 473.

[106] *Lansmann v. Finland* (511/1992), ICCPR, A/50/40/ vol. II (26 October 1994), 66 (CCPR/C/52/D/511/1992) at para. 9.4.

[107] *Mahuika v. New Zealand*, *supra* note 104, at para. 9.5.

[108] Note that these principles appear comparable to some of those found in Canadian law and discussed further below.

[109] General Comment No. 23, *supra* note 105, para. 3.1.

[110] *Ibid.*, at paras. 3.0, 3.1 and 3.2.

This might mean, for example, that any legal or policy mechanisms used to attempt to uphold indigenous control over traditional knowledge might have to give way to the rights of all individuals, whether indigenous or non-indigenous, to enjoy the benefits of scientific discovery or to enjoy the highest attainable standard of physical or mental health.[111] Since the collective rights of indigenous peoples have not been elaborated in a widely accepted form internationally, a framework for the determination of the appropriate principles, priorities or balance to be applied in cases of conflict between individual and collective rights are also underdeveloped.

The Inter-American Human Rights System

Indigenous rights have been considered by the Inter-American Court on Human Rights (the IA Court) and the Inter-American Commission on Human Rights (IA Commission), both of which are established under the *Inter-American Convention on Human Rights* (IACHR). Canada is not a Party to the IACHR, but as a member of the Organization of American States (OAS), is subject to the *American Declaration of Rights and Duties of Man* (the American Declaration). Individuals can lodge complaints with the IA Commission against OAS member States on the basis of violations of the articles of the Declaration. Reports by the Commission about the merits of such complaints have no binding force, but carry moral weight internationally.

Both the IA Court and the IA Commission have taken a keen interest in the rights of the indigenous peoples of the Americas. To date, the cases concerning indigenous peoples that have come before these bodies have addressed questions about indigenous rights to real property. Given the relationship between traditional knowledge and indigenous traditional lands, these cases could prove to be significant, including in relation to questions about access to genetic resources on such lands. An important case considered by the IA Court, for example, resulted in the suspension of a forestry concession to a foreign company operating in Nicaragua, pending the demarcation and titling, in accordance with Nicaragua domestic law, of the traditional lands of the indigenous group concerned.[112] Also of interest from the perspective of the relationship between traditional knowledge and the cultural rights recognized under the American Declaration, the Commission has decided that it can consider a complaint by an aboriginal person against Canada that is based on an argument that traditional trading practices between different indigenous groups across national boundaries is protected as a cultural right.[113]

In general, the IA Commission and IA Court have demonstrated a willingness to try to interpret the words of the IACHR and of the American Declaration to accommodate the communal nature of indigenous peoples' concepts of their rights, at least in relation to the right to property described in those instruments.[114] Although neither has considered complaints specifically addressing rights to control traditional knowledge, the flexibility and interest they have shown in relation to indigenous peoples' claims is noteworthy, and makes the Inter-American system particularly significant in the development of international law respecting indigenous rights.

---

[111] Found in Article 12 and Article 15 of the ICESCR.

[112] *The Case of the Mayagna (Sumo) Awas Tingni Community*, *supra* note 85.

[113] See Inter-American Commission on Human Rights Report No. 74/03 on admissibility in relation to Petition 790/01. *Grand Chief Michael Mitchell v. Canada*, October 22, 2003. The Report is available at: http://www.cidh.org/annualrep/2003eng/Canada.790.01.htm, last viewed on March 24, 2004. The Commission has determined admissible the petitioner's complaint that restrictions on his ability to conduct cross border trade without the payment of customs duties and other taxes is contrary to the cultural rights provisions of the *American Declaration of the Rights and Duties of Man*. The merits phase of the complaint will now proceed. Article XIII therein states that: "Every person has the right to take part in the cultural life of the community, to enjoy the arts, and to participate in the benefits that result from intellectual progress, especially scientific discoveries. He likewise has the right to the protection of his moral and material interests as regards his inventions or any literary, scientific or artistic works of which he is the author."

[114] *The Case of the Mayagna (Sumo) Awas Tingni Community*, and the Reports on the *Mary and Carrie Dann* case and *Maya Indigenous Communities of the Toledo District* case each address indigenous rights to real property. (All supra note 85) The right to property that is found in the IACHR and American Declaration are not identical but have been interpreted in the foregoing cases to similarly protect indigenous collective rights to land. The right to property described in the two instruments may be interpreted to include intangible property, although this topic has not yet arisen before the IA Court or IA Commission. (See IACHR, Article 21 and American Declaration Article XXIII). In the *Yanomami Case*, Report 12/85, the IA Commission recognized the collective rights of the Yanomami people of Brazil to the delimitation and demarcation of Yanomami territory.

The Right to Self-Determination

The right to self-determination of peoples has an important role to play in the determination of the existence and scope of indigenous rights. Accordingly, despite the fact that it is described in Common Article 1 of the two Covenants, it is discussed here as a separate matter, rather than in connection with Article 15 of the ICESCR and Article 27 of the ICCPR above.

In her history of the Paris Peace Conference of 1919 at which the Treaty of Versailles was negotiated and Europe, the Middle East, and other parts were carved up by the dominant powers at the time, Margaret MacMillan quotes then U.S. President Woodrow Wilson, an ardent supporter of the principle of self-determination of peoples, a novel concept at the time, as saying: "When I gave utterance to those words ('that all nations had a right to self-determination'), I said them without the knowledge that nationalities existed, which are coming to us day after day."[115] Of course, it should have come as no surprise that the notion that peoples should be free to determine their political status and to pursue their economic, social and cultural development would be embraced wholeheartedly by those who felt oppressed or otherwise ill governed during a period of imperial decline.

During much of the 20th century the principle of self-determination, now enshrined as a right of peoples in Common Article 1 of the ICCPR and ICESCR, was viewed as a decolonizing principle. However, in relation to indigenous peoples, it is regarded somewhat differently. Indigenous claims to self-determination are certainly a challenge to the view that the State is the dominant body to which allegiance is owed and identity defined, but they do not necessarily include a complete rejection of its role. Kingsbury notes that "[m]ost of the groups participating in the international indigenous peoples movement,... expect to continue in an enduring relationship with the State in which they presently live."[116]

International law does not yet define who are the "peoples" that have a right to self-determination, or what the right itself consists of. According to the traditional view mentioned above, the "peoples" referred to in Common Article 1 is understood to apply to the entire population of existing States and to "peoples" living in colonial situations. The right was equated to a right of independent statehood. In this traditional approach to self-determination, the entire population of, for example Canada, constitutes a people for the purposes of Article 1. Indigenous collectivities and other sub-national groups in Canada participate in the exercise of this right of self-determination as part of the people of Canada, with a right to vote and otherwise participate in the governance process, and possibly even with the benefit of special measures to address their specific needs or interests.

The Supreme Court of Canada opined about the international right of self-determination in *Reference Re: Secession of Quebec*. In its decision, the Court noted that the "precise meaning of the term "people" remains uncertain", and did not offer its own definition. It did note, however, that in certain circumstances a "people" may include "only a portion of the population of an existing state" and the term "does not necessarily mean the entirety of a state's population".[117]

In a discussion paper presented at the 6th session of the UN Working Group on Minorities, Asbjorn Eide notes that it is still a matter of debate whether indigenous peoples are "peoples" in the sense of Common Article 1, and raises questions about the content of the right, especially as regards the concept of territorial sovereignty. Eide points out that discussion of the relationship between Common Article 1 and the reference to self-determination in the draft declaration has been one of the most controversial elements in that process:

> 13. A long debate took place ... [at] the working group... Representatives of indigenous groups

---

[115] M. MacMillan, *Paris 1919*, 2003, at 12.

[116] B. Kingsbury, 2001, *supra* note 63, at 91.

[117] [1998] 2 S.C.R. 217, at para. 123, and para. 124, respectively. Simply qualifying as a "people" under international law is not necessarily accompanied by a right to secede or otherwise be self-governing. Critical in that regard is the existence of circumstances of oppression against the "people" in question.

> argued in favour of a full-fledged right to self-determination, though that did not necessarily mean that the right would be used to secede from the States of which they now formed part. Representatives of Governments were either opposed to inclusion of the right to self-determination or sought to give it a more limited meaning than was given to that right in the context of decolonisation.
>
> 14. Two revised understandings of the right to self-determination are under discussion. One concerns so-called "internal" self-determination which essentially refers to the right to effective, democratic governance within States, making it possible for the population as a whole to determine their political status and pursue their development. The other seeks to equate the right to self-determination with the right to some – but unspecified – degree of autonomy within sovereign States.[118]

Eide suggests that notions of territorial autonomy and cultural autonomy should generally be kept separate conceptually and in practice:

> ...it is difficult to accept a principle of territorial autonomy based strictly on ethnic criteria, since this ran counter to the basic principles of equality and non-discrimination between individuals on racial and ethnic grounds. There are, on the other hand, strong arguments in favour of forms of cultural autonomy which would make it possible to maintain group identity.[119]

However, he goes on to note that "what is special for indigenous peoples is that the preservation of cultural autonomy requires a considerable degree of self-management and control over lands and other natural resources".[120] In other words, it is difficult to disassociate the notion of cultural autonomy from that of territorial autonomy in the development of an understanding about the right to self-determination as applied to indigenous groups. This means that many of the most vexing conceptual challenges related to the application of this right to indigenous peoples cannot easily be set aside on the basis that traditional knowledge is really about cultural autonomy, particularly in light of the close relationship between traditional knowledge, innovations and practices, and land based activities.

Questions concerning an indigenous peoples' right to self-determination have received a great deal of attention during the meetings of the WGDD.[121] There, discussion about the right to self-determination is framed by article 3 of the Draft Declaration, which states:

> Indigenous peoples have a right to self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.[122]

States and indigenous representatives have focused their discussions on the relationship between Article 3 and Common Article 1 of the two Covenants, the scope and content of the right to self-determination as exercised by indigenous collectivities within existing democratic States, and the relationship between the rights of individual members of indigenous collectivities and the rights of the collective. More generally, the concept of a right of self-determination of indigenous peoples raises a number of difficult issues, including the following: who is an indigenous "people"; who forms the collective; can an indigenous collectivity be a people if they do not have a land base; can a right of self-determination be applied differently to different indigenous peoples within one State; can the right be exercised while respecting the political, constitutional and territorial integrity of the State; and what is the appropriate balance to be achieved between the rights of individuals and those of the collective?[123]

---

[118] UN Commission on Human Rights, *Working paper on the relationship and distinction between the rights of persons belonging to minorities and those of indigenous peoples*, E/CN.4/Sub.2/2000/10, paras. 13 and 14.

[119] *Ibid.*, para. 15.

[120] *Ibid.*

[121] The specific application of the right to self-determination to indigenous peoples has also been discussed by the Committee for the Elimination of Racial Discrimination and by the Committee on Human Rights. See *Right to self-determination: 23/08/96, CERD General recommendation 21, (General Comments)*, 48th session, 1996, where at para. 5 the Committee states: "Also, Governments should consider, within their respective constitutional frameworks, vesting persons belonging to ethnic or linguistic groups comprised of their citizens, where appropriate, with the right to engage in activities which are particularly relevant to the preservation of the identity of such persons or groups." The Human Rights Committee linked the issue of self-government in Canada with the right to self-determination in its concluding observations on Canada's fourth periodic report to the Committee (CCPR/C/79/Add.105, at para. 8). In its concluding observations on Norway's fourth periodic report, the Committee called upon Norway to report on the Sami peoples' right to self-determination (CCPR/C/79/Add.112, at para. 17).

[122] UN draft Declaration, *supra* note 84.

These issues may appear to be tangential to questions about rights respecting a community's knowledge, but they are relevant to the development of an understanding about how claims to "traditional knowledge rights" relate to claims to a right to self-determination. The lack of consensus internationally about the scope and content of a right to self-determination for indigenous peoples therefore makes it challenging to rely on this right as a basis for TK protections. An indigenous community, for example, claiming that the misuse of elements of its traditional knowledge by a third party researcher is contrary to its right to self-determination may find that it is not a "people" for the purposes of such a right based on a careful analysis of applicable international law. Another community claiming that information disclosed to a third party by one of its members is nevertheless still subject to community control on the basis of a right to self-determination might find that any efforts to restrict an individual's ability to share information for certain purposes, such as personal health and well-being, conflict with applicable international human rights law.[124]

D. Summary

A right of indigenous peoples to control traditional knowledge does not yet exist in any widely accepted form at international law. Although it can be said that an indigenous community can control knowledge that it holds simply by refusing to disclose it, it is not clear what a community could do from a rights based perspective to restrict its members from sharing information with third parties, or to restrict third parties from using traditional knowledge that is already in the public domain.

By ratifying the CBD, 188 States have accepted a somewhat qualified obligation to respect, preserve and maintain indigenous knowledge, innovations and practices associated with the conservation of biological diversity. Although the CBD is not itself a human rights instrument, "rights talk" respecting TK and related issues such as culture, traditional lands and self-determination, is increasingly common in decisions of the COP and relevant CBD working groups.

The sources that are available to better appreciate the basis for such "rights talk" appears to be somewhat thin: (1) internationally recognized human rights found in the ICCPR and ICESCR do not include collective rights, indigenous rights specifically, or a right to control TK, although Article 27 of the ICCPR could be relevant to complaints arising from impacts on an indigenous person's ability to enjoy his or her culture in community with others, possibly including traditional knowledge, and can be the subject of judicial proceedings in relation to countries that have accepted the optional protocol;[125] (2) although the treaty bodies interpreting the IACHR and *American Declaration of Rights and Duties of Man* have shown flexibility and interest in relation to indigenous peoples issues, traditional knowledge has not yet featured in complaints before them; (3) ILO Convention 169 is not widely ratified and does not address the right to self-determination of peoples or any rights to control TK specifically; (4) the draft Declaration remains mired in slow debate, as the mandate of the WGDD draws to a close;[126] and (5) the right to self-determination requires further elaboration and analysis before its application to indigenous peoples will be widely embraced, or before the implications of its application will be well understood by governments and indigenous peoples.

Despite these limitations, each of these potential sources of rights provide fodder for arguments that inform the claims made by indigenous representatives, as very narrowly canvassed above. Similar limitations in relation to international law present challenges to any claim to international indigenous rights, let alone those in the domain of TK. This has not stopped international and domestic judicial bodies from drawing guidance from international legal instruments and international policy developments that are viewed by them to be relevant to indigenous peoples' claims, and to be possible sources of customary international law.[127] Although evolving international norms respecting the rights of indigenous peoples may not provide clear or comprehensive obligations, they nevertheless provide some guidance for States that wish to undertake biotechnology policy making with a view to impacts on indigenous interests. This is particularly true for a country like Canada that is a Party to the CBD and that participates actively in international processes at which indigenous peoples' rights are being discussed, elaborated and analyzed.

---

[123] The reports of the Chairperson-Rapporteur of the UN Working Group on the Draft Declaration on the Rights of Indigenous Peoples indicates that many States do not accept the principle that all indigenous collectivities have a right to self-determination. See E/CN.4/1996/84; E/CN.4/1997/102; E/CN.4/1998/106; E/CN.4/1999/82; E/CN.4/2000/84; E/CN.4/2001/85; E/CN.4/2002/98; E/CN.4/2003/92; and E/CN.4/2004/81.

[124] A helpful and extensive discussion of the relationship between individual and group rights in the Canadian Constitution is contained in: J. Arbour, "The Protection of Aboriginal Rights within a Human Rights Regime: In Search of an Analytical Framework for section 25", April 4, 2003. Copy on file.

[125] This includes Canada, which ratified the optional protocol in 1976.

[126] It may be renewed for an additional period to give participants an opportunity to bring discussions about it to a close, either with the adoption of a declaration or with clarification that the draft has no status at international law in the opinion of the members of the UN.

The available guidance can be conservatively summarized as follows: (1) indigenous peoples and indigenous issues have been given a special status in international negotiation processes relevant to their interests, suggesting that their claims enjoy a level of recognized merit; (2) indigenous individuals are entitled to the human rights recognized at international law – treaty bodies are considering complaints lodged by indigenous individuals, even though the international human rights instruments they are empowered to interpret do not address indigenous rights in specific terms; (3) the notion that indigenous peoples have collective rights, including a right to self-determination in some form, are being elaborated internationally, and are increasingly accepted by the international community as a basis for further discussion and norm creation, although the appropriate balance between collective and individual rights has not been resolved, and any descriptions of such rights are not yet widely accepted; (4) the special relationship that indigenous people have with the land, and with their cultural practices and traditions is a significant element in discussions about international indigenous issues; and, (5) most broadly, taken together, developments internationally suggest that it is increasingly accepted that ways should be found to respect indigenous people and communities in relevant law and policy making. However, in doing so, States must also respect the human rights of all people and weigh other important public policy interests. Each of the foregoing "guiding elements" has some relevance to questions about the existence of an indigenous right to own and control traditional knowledge.

With respect to the issue of biotechnology and traditional knowledge more specifically, it can be stated that: (1) the many countries that have ratified the CBD, including Canada, have taken on a number of obligations respecting traditional knowledge; (2) indigenous issues are at the centre of international debate about whether and how traditional knowledge should be addressed in international intellectual property regimes, access and benefit sharing approaches, and in environmental conservation measures, among other topics; (3) indigenous people have been given a role in the identification of relevant issues and development of solutions respecting TK in various venues in which their level of participation is elevated to such an extent that it is not all that dissimilar from that of States; (4) traditional knowledge is increasingly being associated with "rights talk"; and (5) although they are imperfect, undeveloped by international or domestic judicial bodies in relation to their application to TK, or, in the case of the draft Declaration, for example, incomplete and possibly destined to remain that way, the sources of international norms respecting indigenous rights can be used to develop a better understanding about what the "rights talk" respecting TK is all about.

Indeed, all interested parties must be aware that judicial bodies may well look to the sources discussed above for guidance if questions about the existence, nature and scope of "TK rights" are put to them. Although the status at law (or lack thereof) of the various sources should determine the weight they are to be given, if any, the fact that some have no status does not bar judges from considering them as relevant background, or governments and other interested parties from looking to them for guidance as to how TK should be addressed in relevant laws and policies.

7.4.3 The Domestic Level

It is important to recall that the legal, political, economic, social and cultural realities of aboriginal people in Canada are incredibly diverse. A careful and comprehensive assessment of any rights relevant to the issue of traditional knowledge and biotechnology would have to focus independently on each of the three major indigenous groups in Canada – the Inuit, Métis and First Nations, which are referred to as the "aboriginal peoples of Canada" in the *Constitution Act, 1982*.[128] Such an assessment might also have to distinguish further between those who have "Indian status" under the *Indian Act* and those who do not; those who live on or off reserve; those who live in cities and those who live in remote communities; those whose communities are party to historic treaties or modern land claims or self-government agreements; and possibly, those individuals or communities who have managed to maintain and enrich their cultural traditions since European contact from those who, with the passage of time and the challenges posed by a troubled history of interactions with non-indigenous society, have not. These important details are well beyond the scope of this chapter. Instead, the following discussion will more generally outline the contours of aboriginal and treaty rights and their analysis under Canadian law, with a view to traditional knowledge issues. As was the case in relation to the international discussion above, the focus is on the question whether there may be a basis in Canadian law for an assertion that aboriginal people have a right to own and control their traditional knowledge.

---

[127] *Supra* notes 85 and 86.

Any answer to this question is highly speculative because Canadian courts have not yet been asked to consider whether such a right exists. Further, as discussed below, under Canadian law, the existence of aboriginal rights are determined based on the particular facts and particular circumstances relevant to the group claiming the right. A determination that one group has certain aboriginal rights based on the specific facts at issue does not necessarily mean that any other aboriginal group in Canada has those same rights. The structure of Canadian law respecting aboriginal rights makes it impossible to make any general pronouncement concluding that they do or do not exist.

Further, it should be noted that due to the nature of traditional knowledge, which is regarded as a collective rather than individual good, the focus of this section is on collective aboriginal and treaty rights, rather than on the human rights that are protected under Canadian domestic law. An overview of the Canadian human rights framework is set out in the first chapter of this paper and need not be repeated here. However, subsection C below will briefly address the framework available to address conflicts that might arise between individual human rights and collective aboriginal rights.

A. The Domestic Biotechnology, Rights and TK Context

Canada's active participation in international fora in which discussion about traditional knowledge figures prominently is relevant to a description of the domestic context for TK issues. International legal and policy developments respecting TK rights can be used domestically to inform, for example, legal and policy initiatives, legal arguments in litigation, community approaches to TK protection and preservation, and positions taken in land claim and self-government negotiations. Of particular relevance, Canada must take steps to implement obligations it accepted by ratifying the CBD, including those found in Article 8j, which is discussed above. Due to the connections that exist between traditional knowledge and broader matters of interest to aboriginal people, many of the policy and legal activities undertaken by Canada in relation to aboriginal issues may be relevant in this regard, including those in the field of claims settlement, the environment, cultural promotion and protection, and political and economic development.

The TK agenda in Canada has been driven by a combination of forces. Principally, these include (1) the interest, shared by governments and aboriginal peoples, in understanding how traditional knowledge and practices fit within the evolving domestic legal and policy framework, (2) self-government and land claim negotiations, (3) requirements found in some legislation respecting the utilization of traditional knowledge,[129] and (4) general considerations about the need to respect, preserve and maintain aboriginal cultures, including languages, traditional activities and practices, and world views.[130]

---

[128] *Constitution Act, 1982*, s. 35(2).

[129] Such legislation includes the *Species at Risk Act*, 2002, c.29, which includes provisions respecting the establishment of a sub-committee on traditional knowledge to assist in the determination of whether any particular species is at risk in accordance with the Act, the *Yukon Environmental and Socio-economic Assessment Act*, 2003, c.7, which suggests that traditional knowledge is a feature of a complete information gathering process in relation to proposed projects, the *Canadian Polar Commission Act*, 1991, c.6, which defines "knowledge" as including traditional knowledge, which is within the mandate of the Commission to consider and disseminate within the scope of its activities to promote knowledge about the North, the *Canadian Environmental Assessment Act*, 1992, c.37, which indicates that traditional knowledge should be used in environmental assessments, and the *Canadian Environmental Protection Act*, 1999, c.33, which also refers to traditional knowledge as a relevant source of information about environmental issues.

To date the link between biotechnology and TK has been a less prominent driver than the matters listed above. This may be partly because it is not yet clear whether genetic resources from organisms found in Canada will be fruitful for biotechnology researchers, although the country does offer harsh environments in some abundance, which are often of interest.[131] This may change now that the Parties to the CBD have initiated a process for the negotiation and elaboration of an international access and benefit sharing regime respecting genetic resources in which indigenous groups will play a key role.[132]

Canada's domestic policy making process with respect to access to genetic resources will proceed at the same time that the "international regime" discussions take place among CBD Parties. Currently there is something of a legal and policy *tabula rasa* in this area domestically. There are virtually no specific controls on bioprospecting in Canada. The legal controls that do exist depend on a combination of the category of resource sought (for example, whether *in situ* or *ex situ*),[133] and whether the resource is on public lands, where a combination of federal, territorial and provincial legislation might be relevant, private lands, where trespass laws are applicable, or on Indian reserves or lands owned by aboriginal communities pursuant to land claims agreements, where specific access rules may apply.[134]

It is probably impossible to come up with a credible estimate of the potential value, in financial terms, that could be derived from the traditional knowledge of aboriginal people in Canada by the biotechnology industry. Regardless, the following factors mean that developments in this field could have an important impact on aboriginal law and policy making, as well as on the negotiation of agreements intended to resolve outstanding land and self-government issues: (1) a link clearly exists between biotechnology and TK; (2) this link is the focus of some debate internationally through a variety of intergovernmental fora; and (3) the debate is significant to Canada both because of the existence of its aboriginal population and because of the size of its biotechnology industry.

Meanwhile, regardless of developments in the field of biotechnology, the consideration of the appropriate legal and policy framework within which to situate aboriginal culture, including languages, traditional knowledge, customary laws and practices, and world views in general, will continue to increase in importance in Canada. Guided by the recognition given to aboriginal and treaty rights under the Canadian Constitution,[135] case law that is particularly relevant to aboriginal people will continue to be developed by the courts and by litigants; various tools, such as the negotiation of agreements, will be utilized to create space for aboriginal people to fulfill their goals; and public policy making, although driven by the priorities of the government of the day, will continue to confront fundamental questions about the nature of reconciliation, the meaning of shared citizenship within a multidimensional state, and the challenges posed by the diversity that exists in the aboriginal community – not to mention in Canada as a whole. This evolving process will over time have continuous relevance to biotechnology related law and policy, as it will with respect to other important Canadian policy priorities of the day.

B. Aboriginal Rights under Canadian Domestic Law

Canada has a fairly well developed legal and policy framework respecting many aboriginal issues. However, existing aboriginal rights are not actually well defined. Indeed, uncertainty in this regard, together with the encouragement of the Courts,[136] has contributed to the adoption of policy approaches that favour the negotiation of settlements respecting aboriginal rights over litigation. The Government of Canada has developed policies to guide it in the negotiation of self-government agreements, comprehensive land claims, and specific claims respecting unfulfilled treaty obligations.[137] The resolution of self-government issues and land claims is discussed further below.

---

[130] By way of illustration, a stated objective in the government's *Copyright Act* reform agenda is to address traditional knowledge. See http://strategis.ic.gc.ca/epic/internet/incrp-prda.nsf/en/rp00877e.html, last viewed on March 25, 2004.

[131] For a discussion about how bioprospecting came to Yellowstone National Park, and the impact a major biological resource-based discovery had on park management, see H. Doremos, "Nature, knowledge and profit: the Yellowstone bioprospecting controversy and the core purposes of America's national parks", (1999) 26 *Ecology Law Quarterly* 401. Following the discovery, Yellowstone developed a model agreement addressing research on the Park's biological resources. A copy of this agreement is on file.

[132] *Supra*, note 76.

[133] "*In situ*" refers to genetic material contained in its living organism and located in its natural habitat. "*Ex situ*" refers to genetic material that is still in its natural state, but is no longer in its natural habitat.

[134] H. Mann, *Access to Genetic Resources in Canada: The Legal Framework, Final Report (Draft)*, March 12, 2002, prepared for the Biodiversity Convention Office, Environment Canada. Copy on file.

[135] Section 35(1) of the *Constitution Act, 1982* states: "The existing aboriginal and treaty rights of the aboriginal peoples of Canada are hereby recognized and affirmed."

Existing aboriginal and treaty rights are recognized and affirmed in section 35(1) of the *Constitution Act, 1982*. A body of case law is growing in Canada in which the courts have developed tools for the assessment of the existence, nature and scope of the "aboriginal rights" that are referred to in section 35, but left undefined. The analysis to be used to determine whether aboriginal rights exist in a specific case is set out in section C below.

"Treaty rights" are defined in the many historic treaties[138] and growing number of self-government and comprehensive land claims agreements that have been given constitutional protection under section 35.[139] Treaties define certain rights of aboriginal people living in most parts of Canada. Generally they involve a surrender of undefined rights in exchange for some form of consideration. Historic treaties were generally brief and often addressed issues such as peace and friendship, hunting, gathering and fishing, and reserve land allotments. Modern treaties are detailed and comprehensive, addressing such matters as self-government powers, governance structures, land and resource allocations, hunting, gathering and fishing, and land and resource co-management. Modern land claim negotiations are generally used to try to resolve outstanding claims with respect to those parts of the country in which aboriginal rights were generally not addressed in historic treaties, such as British Columbia, the territories north of 60 degrees North latitude, northern Quebec and Labrador.[140]

Litigation in Canada has tended to focus on the existence and nature of aboriginal title, issues about treaty interpretation, and the existence of aboriginal or treaty rights to undertake traditional activities, such as hunting, gathering and fishing, all on a case by case basis. While aboriginal knowledge finds indirect expression in the activities that have so far been the subject of litigation, the cases have focused on impacts on a particular aboriginal group's ability to go out and physically practice an activity based in historic traditions rather than on impacts on a group's ability to hold or control knowledge intimately connected to certain activities or places.[141]

Out of aboriginal and treaty rights litigation, a body of law has developed that provides guidance as to when aboriginal and treaty rights exist, whether such rights can be infringed by government action, and when such infringement can be justified. This body of law is familiar to counsel working in the field of aboriginal law, and has been described in detail elsewhere. Accordingly, an extensive discussion need not be included here. Instead, a general overview follows.

---

[136] *Delgamuukw v. British Columbia* [1997] 3 S.C.R. 1010, at para. 186, where Lamer C.J. stated: "Finally, this litigation has been both long and expensive, not only in economic but in human terms as well. By ordering a new trial, I do not necessarily encourage the parties to proceed to litigation and to settle their dispute through the courts. As was said in [*R. v. Sparrow* [1990] 1 S.C.R. 1075, at 1105], s. 35(1) 'provides a solid constitutional base upon which subsequent negotiations can take place'. Those negotiations should also include other aboriginal nations which have a stake in the territory claimed. Moreover, the Crown is under a moral, if not a legal, duty to enter into and conduct those negotiations in good faith. Ultimately, it is through negotiated settlements, with good faith and give and take on all sides, reinforced by the judgments of this Court, that we will achieve what I stated... to be a basic purpose of s. 35(1) — 'the reconciliation of the pre-existence of aboriginal societies with the sovereignty of the Crown'. Let us face it, we are all here to stay."

[137] By name, they are the *Comprehensive Land Claims Policy*, *Aboriginal Self-Government Policy*, and *Specific Claims Policy*. Information about them is available at: http://www.ainc-inac.gc.ca/ps/clm/index_e.html, last viewed March 25, 2004.

[138] "Historic treaties" are those negotiated by aboriginal groups and representatives of the British Crown roughly from the 18th century to the early part of the 20th century.

[139] Not all self-government agreements that have been concluded to date in Canada are constitutionally protected under section 35. For example, there are fourteen First Nations in Yukon. Just over half of them have concluded self-government agreements that do not address the question of their constitutional status. When the parties to self-government or land claims agreements agree that the agreements are constitutionally protected, they include a provision to this effect.

[140] The first "modern claims agreement", the *James Bay and Northern Quebec Agreement* was concluded in 1975 by the Crees of Quebec, the Government of Quebec and Canada. Since then, land claims agreements have been concluded with the Inuvialuit, Sahtu Dene, Gwitchin and Dogrib (or Tlicho) of NWT, with the Inuit of Nunavut, which also resulted in the establishment of the new territory in 1999, with the Nisga'a of BC, and with more than half of the fourteen Yukon First Nations. A number of self-government agreements have also been concluded. Those containing the broadest law making authorities are with the Nisga'a and the Tlicho.

[141] For discussion, see Christie, *supra* note 29 and D Robbins, "Aboriginal Custom, Copyright & the Canadian Constitution", 1999, available at http://www.ubcic.bc.ca/docs/Robbins.pdf, last viewed March 31, 2004.

With the addition of section 35 to the Constitution, the Crown's power to unilaterally extinguish aboriginal or treaty rights prior to 1982 has been curtailed.[142] In a number of important decisions, the Supreme Court of Canada has examined the effect of section 35(1). In essence, existing aboriginal and treaty rights as of 1982 are constitutionally protected. This does not mean that such rights cannot be infringed. The Supreme Court has indicated that aboriginal and treaty rights can be infringed where this can be justified.

The justification analysis involves an assessment of whether (1) a valid legislative objective is served by the infringement, and (2) if a valid legislative objective is found, whether the infringing action is consistent with the honour of the Crown and the fiduciary nature of the *sui generis* relationship between the Crown and the aboriginal peoples of Canada.[143] The Court has provided a fairly extensive list of examples of valid legislative objectives, such as "the development of agricultural, forestry, mining and hydroelectric power, the general economic development [of a province], protection of the environment or endangered species, the building of infrastructure and the resettlement of foreign populations to support these aims."[144]

In many cases, the Crown must engage in meaningful consultations with affected aboriginal communities in order to satisfy the justification test. Failure to consult will not necessarily prove fatal to the Crown's case, but is an element to be considered when determining whether the infringement of the right is justified. Further, in its decision in *Delgamuukw*, the Supreme Court concluded that there is always a requirement to consult, which may in some circumstances require consent, when there is an infringement of existing aboriginal title.[145] The courts have also suggested that there may be a requirement to consult in relation to provincial hunting and fishing regulations that impact on existing rights.[146]

In addition, on November 18, 2004, the Supreme Court of Canada rendered its decisions in two important cases, *Haida Nation v. British Columbia (Minister of Forests)*[147] and *Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)*,[148] which assists in the resolution of a question that had arisen in relation to the justification test and the duty to consult.[149] The question was: are these matters applicable only once aboriginal rights have been established by statute, treaty or court decision, or are they triggered when a *prima facie* case can be made, or even when a claim is simply asserted, that existing aboriginal rights may be infringed by a government decision or activity? In addressing this issue the Court focused on consultation, concluding that a legal duty to consult and in some cases accommodate potential aboriginal rights can apply when the Crown has knowledge of the potential existence of an aboriginal right and contemplates conduct that might adversely affect it. This duty is not part of the justification test, rather its source is in the principle of the honour of the Crown. Prior to these cases, the Supreme Court of Canada had only discussed consultation in the context of established or proven section 35 aboriginal rights.

The foregoing suggests that aboriginal and treaty rights analysis in practice under Canadian law is not about absolutes, it is about balancing sometimes competing interests. Government contributions to efforts to find the right balance must be guided by the honour of the Crown arising from the *sui generis* fiduciary relationship she has with aboriginal peoples.[150] This is in Keeping with the

---

[142] In *R v. Badger* [1996] 1 S.C.R. 771, the Supreme Court of Canada stated that prior to the enactment of s. 35 in 1982 the Crown was empowered to unilaterally modify or alter aboriginal and treaty rights by legislative and other means. This is consistent with the 1990 Supreme Court of Canada decision in *R v. Horseman* [1990] 1 S.C.R. 901, which said that s. 12 of the *Natural Resource Transfer Agreements* between Canada and the three Prairie provinces, enacted without any aboriginal input, effectively extinguished original treaty rights and replaced them with others. The onus of proving that a treaty or aboriginal right has been extinguished via legislation lies with the Crown.

[143] Discussed in *Sparrow, supra*, note 136 and in *Delgamuukw, supra*, note 136, at paras. 161 to 163, among other cases.

[144] *Delgamuukw, supra* note 136, at para. 165.

[145] *Ibid.*, at para. 168

[146] *Badger, supra* note 142 and *R. v. Marshall* [1999] 3 S.C.R. 456.

[147] 2004 SCC 73, aff'g [2002] 2 C.N.L.R. 121, 2002 BCCA 147, additional reasons (2002), 216 D.L.R. (4th) 1, 2002 BCCA 462 (CA).

[148] 2004 SCC 74, rev'g (2002), 211 D.L.R. (4th) 89, 2002 BCCA 59 (CA).

[149] For a discussion of the issues that was referred to by the Supreme Court of Canada in the decisions, see s. Lawrence and P. Macklem, "From Consultation to Reconciliation: Aboriginal Rights and the Crown's Duty to Consult", 79 Cdn. Bar Rev. 252 (2000).

[150] There is a difference between the fiduciary relationship and fiduciary duties. The relationship between the Crown and aboriginal peoples is characterized as a *sui generis* fiduciary relationship, which means that the honour of the Crown is always at stake in its interactions with aboriginal peoples. In specific circumstances, aboriginal communities may have valid reason to believe that the Crown will act exclusively in their best interests, due to statutory obligation, unilateral promise, or mutual agreement. In those cases a fiduciary duty may arise. Breach of a fiduciary duty carries different legal consequences than does a failure to uphold the fiduciary relationship. The Supreme Court of Canada has clarified this distinction. *Wewaykum Indian Band v. Canada*, [2002] 4 S.C.R. 245.

Supreme Court's statement that the purpose of section 35(1) is "the reconciliation of the pre-existence of aboriginal societies with the sovereignty of the Crown."[151]

C. Are There Rights to Traditional Knowledge under Canadian Law?

To date, traditional knowledge has not been the subject of aboriginal rights litigation specifically, but is relevant to land claim and self-government negotiations, and is increasingly addressed in bilateral agreements between resource development companies or researchers and aboriginal communities. Traditional knowledge is also mentioned in some legislation, where it is regarded as a component of complete information gathering processes in relation to environmental and land use matters.[152]

Although advances in biotechnology have not been a driving force in relation to any of these matters, an outline of the ways that traditional knowledge has been addressed, or is affected by or relevant to, aboriginal and treaty rights litigation and self-government and land claim agreements provides some guidance for the construction of a rights based framework for the assessment of biotechnology policy.

(i) Aboriginal Rights and TK

The test for the existence of aboriginal rights was set out as follows by Lamer, C.J. in the Supreme Court's *Van der Peet* decision:

> … in order to be an aboriginal right an activity must be an element of a practice, custom or tradition integral to the distinctive culture of the aboriginal group claiming the right. [para. 46]
>
> […]
>
> The claimant must demonstrate that the practice, custom or tradition was a central and significant part of the society's distinctive culture. He or she must demonstrate, in other words, that the practice, custom or tradition was one of the things which made the culture of the society distinctive — that it was one of the things that truly *made the society what it was.* [emphasis from original][153]

Lamer C.J. went on to state that although the practices, customs and traditions which constitute aboriginal rights may be exercised in a modern form, they should have continuity with the practices, customs and traditions that existed prior to contact with European society….[154]

In its decision in *Delgamuukw*, the Supreme Court elaborated on the concept of aboriginal rights, in particular in relation to the relationship between aboriginal people and their traditional lands. In his reasons for judgment, Lamer C.J. notes that section 35(1) must recognize and affirm both aspects of the existence of aboriginal societies prior to the assertion of Crown sovereignty — the prior occupation of land and the prior social organization and distinctive cultures of aboriginal peoples on that land.[155] The test for aboriginal title enunciated by Lamer C.J. in *Delgamuukw* is similar to the test for the existence of other aboriginal rights, drawing on the historic relationship of the aboriginal group concerned with its traditional lands, but with a requirement that the current occupation of lands have continuity with the historic occupation.[156]

The broad similarities between the tests for aboriginal rights in general and for aboriginal title reflect the Court's view that aboriginal title sits at one end of a spectrum of aboriginal rights. All the rights within the spectrum receive constitutional protection. Lamer C.J. states:

> … aboriginal rights which are recognized and affirmed by s.35(1) fall along a spectrum with respect to their degree of connection to the land. At the one end, there are those aboriginal rights which are practices, customs and traditions that are integral to the distinctive aboriginal culture of the group claiming the right. However, the occupation and use of the land where the activity is taking place is not sufficient to support a claim of title to the land… In the

---

[151] *Delgamuukw*, par. 186.

[152] *Supra* note 129.

[153] *R. v. Van der Peet*, [1996] 2 S.C.R. 507, at para. 55.

[154] *Ibid.*, at paras. 60 to 67.

[155] *Delgamuukw*, *supra* note 136 at para 141.

[156] The tests for existing aboriginal title and existing aboriginal rights are similar, but not identical. For example, with respect to the former, in order to establish title, an aboriginal group must establish that it had exclusive use at the time of Crown sovereignty. The important date in relation to the establishment of aboriginal rights is the time of contact with European society.

> middle, there are activities which, out of necessity, take place on land and indeed, might be intimately related to a particular piece of land… an aboriginal group… may… have a site-specific right to engage in a particular activity… At the other end of the spectrum, there is aboriginal title itself… What aboriginal title confers is the right to the land itself.[157]

The determination of whether aboriginal rights exist in any particular circumstances, or, if they exist, can be infringed, is made under Canadian law on a case by case basis. Accordingly, it is difficult to draw any conclusion regarding the existence of aboriginal rights respecting traditional knowledge in the absence of a fact situation. The following comments are therefore aimed at a general level and are speculative.

Due in part to the difficulty inherent in identifying a particular element or aspect of traditional knowledge as a discrete item that can be the subject of a *Van der Peet* analysis, as compared to a particular activity, it is not easy to predict how a TK right claim would be framed. On the one hand, in *Van der Peet* itself it is difficult to disassociate the TK aspect of the fishing right claimed from the traditional fishing activity that the case addressed. Indeed, it becomes difficult to define an activity in the absence of a description about the knowledge, innovations and practices that inform the manner in which it is carried out. Based on the outline above about what traditional knowledge is, it would seem that aboriginal knowledge, innovations and practices would be part of any aboriginal right that can conceivably be described. Once a particular practice, custom or tradition is found to constitute an aboriginal right, traditional knowledge associated with that practice, custom or tradition might also be protected by section 35.

The same might be said about aboriginal title. As is suggested in various places in this chapter, an integral feature of traditional knowledge is that it has been honed through an intimate relationship with the lands of the people who hold it.

On the other hand, not all aboriginal knowledge, innovations and practices would satisfy the test. Relevant TK would be that which has continuity with pre-contact knowledge, innovations and practices, and that is integral to the distinctive culture of the group claiming the right. Borrows has expressed concerns that the aboriginal rights tests that have been developed by the Supreme Court unnecessarily and inappropriately have the effect of freezing the practices, customs and traditions of aboriginal peoples in historic times.[158] This effect might be a particular concern in relation to traditional knowledge as it is suggested that such knowledge forms part of a comprehensive, interrelated world view. By this view, it is difficult to pull knowledge about a particular plant and its uses, for example, out of the context in which the knowledge is applied or out to the context of the community's relationship with the world around it.

Canadian scholars are investigating whether an aboriginal rights claim respecting tangible or intangible cultural property could be fruitfully made based on the *Van der Peet* analysis. Catherine Bell and Robert Patterson, for example, have argued that in the context of claims to tangible cultural property (such as repatriation of community artefacts), the "right" at stake might be a right to own and pass on property based on customary laws and practices, to the extent such laws and practices can satisfy the test.[159] A challenge that arises in relation to questions about aboriginal rights to cultural property is to describe the right in a way that the courts can work with. Bell and Patterson propose that the courts should increase the flexibility of the basic *Van der Peet* analysis to address cultural property rights because of the importance of such property to aboriginal communities.[160] Flexibility in the activity-based rights analysis in *Van der Peet* has indeed been shown. In *Delgamuukw*, for example, the Supreme Court modified the test for aboriginal rights in order to apply it to questions about the existence of aboriginal title, which is not a right to conduct an activity, but a "right to the land itself."[161]

---

[157] *Delgamuukw, supra*, note 136.

[158] Borrows, *supra* note 16.

[159] C. Bell and R. Paterson, "Aboriginal Rights to Cultural Property in Canada", 3(1) Int'l J. Cultural Property, 167 (1999). Bell and Patterson are leading a Social Sciences and Humanities Research Council of Canada funded project on aboriginal cultural heritage. The research program is described as follows on its website: "This research program… will examine Canadian legislation affecting ownership, protection and control of First Nation cultural heritage and develop strategies for reform. The research has four primary objectives: to disseminate information about the existing legal regime; to facilitate respect for, and understanding of, First Nations concepts of property and laws affecting cultural heritage; to assist First Nation community partners collect and develop archival and educational resources on local indigenous laws and cultural heritage; and to critically analyse domestic law and provide recommendations for reform." More information about the project is available at: http://www.law.ualberta.ca/research/aboriginalculturalheritage/index.htm, last viewed on March 25, 2004.

[160] *Ibid.*, at 182.

A Canadian case that did consider tangible cultural property was *Kitkatla*, which concerned the issuance of lumber permits by provincial officials in a part of British Columbia where a significant number of culturally modified trees were found.[162] Like the courts below, the Supreme Court of Canada found the evidence to support a claim to aboriginal rights to such cultural objects to be too thin to make a ruling on that issue. Instead, the Court's attention was focused on the question of whether B.C. had the requisite authority pursuant to the constitutional division of powers to regulate heritage objects. The Supreme Court upheld the decisions of the B.C. courts concluding that the province had the authority to pass its *Heritage Conservation Act*, which supported the protection of some, but not all, of the culturally modified trees, with a view to balancing conservation with economic development. The Supreme Court did state, however, that "[h]eritage properties and sites may certainly, in some cases, turn out to be a key part of the collective identity of people", and that in "some future case, it might very well happen that some component of the cultural heritage of a First Nation would go to the core of its identity in such a way that it would affect the federal power over native affairs and the applicability of provincial legislation."[163]

Gordon Christie has considered the applicability of the *Van der Peet* approach to intangible aboriginal knowledge, such as that expressed in storytelling. He argues that although the test was developed with a view to its application to discrete identifiable activities — what could be called 'bricks and mortar' claims — it may work well in relation to "narratives, ceremonies and other intellectual products" of aboriginal communities that more closely define the "essential being of the Aboriginal life-world."[164]

Christie suggests that in order to fall within the scope of the analysis, the right at issue could be cast as a right to the "exclusive control and use, by the Aboriginal community," of the traditional knowledge.[165] This description of the right at issue is reflective of the indigenous statements identified above in the section on international law. It would then have to be demonstrated that the interest in exclusive control and use existed pre-contact and continues to this day. In light of the fact that so much traditional knowledge is in the public domain, this part of the test might be difficult to meet. Christie argues that the fact that aboriginal communities were willing to share their knowledge in the past, however, does not mean that they consented to its use by others for any purpose, and should not preclude an argument of continued exclusive control.[166] Aboriginal title case law might provide some support for Christie's view. The relevance of exclusivity is a consideration that the courts have addressed in the context of claims to aboriginal title, in which exclusive occupation is relevant. In that context, exclusive occupation need not necessarily mean "occupation that prohibits entry by all others."[167]

Christie concludes by arguing that although an argument might successfully be made that aboriginal knowledge can find some protection under Canadian law through the application of a *Van der Peet* analysis and section 35, this is not really the goal from the perspective of aboriginal people. For Christie, the objective is to uphold the view that "Aboriginal communities are best situated, and best able, to control the dissemination of culturally significant information."[168] Further, he argues that many communities are already doing so, at least with respect to knowledge that has not already become widely available.[169]

---

[161] *Delgamuukw, supra* note 136, at para. 140. In *R v. Powley* [2003] 2 S.C.R. 207, the Supreme Court of Canada applied an aboriginal rights analysis to the question whether Métis have such rights, which required some modification of the standard test.

[162] *Kitkatla Band v. British Columbia (Minister of Small Business, Tourism and Culture)*, [2002] 2 S.C.R. 146. "Culturally modified trees" are trees that "have been altered by aboriginal people as part of their traditional use and have cultural, historical and scientific importance for" the First Nations that modified them. (*Kitkatla*, at para. 1)

[163] *Ibid.*, at para. 78. For a discussion that predates the decision of the Supreme Court, see C. Bell, "Protecting Indigenous Heritage Resources in Canada: A Comment on Kitkatla v. British Columbia", 10(2) Int'l J. Cultural Property 246 (2001).

[164] Christie, supra note 29, at para. 74.

[165] *Ibid.*, at para. 75.

[166] *Ibid.*, at paras. 79 to 80.

[167] For a discussion about the exclusivity requirement, see *Delgamuukw, supra* note 136, at paras. 155 to 159. At para. 155 Lamer C.J. states: "Finally, at sovereignty, occupation must have been exclusive. The requirement for exclusivity flows from the definition of aboriginal title itself, because I have defined aboriginal title in terms of the right to *exclusive* use and occupation of land. Exclusivity, as an aspect of aboriginal title, vests in the aboriginal community which holds the ability to exclude others from the lands held pursuant to that title." Later, at para. 157, he adds: "A consideration of the aboriginal perspective may also lead to the conclusion that trespass by other aboriginal groups does not undermine, and that presence of those groups by permission may reinforce, the exclusive occupation of the aboriginal group asserting title."

Aboriginal rights litigation generally arises in cases in which an aboriginal group asserts that they have rights that are infringed by an activity authorized by government contrary to law. In the case of TK, for example, a relevant case might take the form of an assertion that the use of sacred traditional knowledge by a government biotechnology research institute infringes an aboriginal right to exercise control over the way such knowledge is used. The mere assertion of the aboriginal right at stake is not the end of the matter. In order for the activity to be contrary to law, it must fail the justification test described above. The activity would meet the test if it satisfied the valid legislative objective test and was carried out in a way that upholds the honour of the Crown. Generally speaking, consultation is a tool that can be used to satisfy the second part of the justification analysis, and in many situations is a good policy objective regardless whether it is actually legally required in a specific case.

Some Comparative Examples from Other Legal Systems

Cases related to traditional knowledge are arising in other countries. They may not offer direct guidance as to how the topic would be addressed by Canadian courts, but may foreshadow how claims related to it could arise. In New Zealand, for example, the Maori have asserted a claim essentially to all of the flora and fauna in the country, including a claim to a right to have their traditional knowledge and cultural property protected.[170] On the one hand, the claim has been asserted on the basis of the words of the foundational document governing the relationship between Maori and New Zealand, the Waitangi Treaty, so any decision may have limited value in Canada from a comparative basis, at least as a source of direct guidance to Canadian courts. On the other hand, at a more general level the claim reflects the same kind of comprehensive and holistic world view that is expressed by aboriginal groups in Canada and, due to its broad scope, reinforces that if TK based claims are ever made here, they would have broad implications.

In Australia, a few cases have considered issues about the misuse of tangible cultural property in the context of copyright law. One case, *Bulun Bulun*, involved a suit by an aboriginal artist and community against a private company that had reproduced the artist's work without permission.[171] The artist made a claim on the basis of the Australian *Copyright Act*, which was successful. In the same lawsuit, counsel for the community had difficulty framing a claim within the scope of Australian copyright and common law, and eventually abandoned an argument that the knowledge represented in the artwork at issue was an aspect of aboriginal communal title.[172]

Instead, the Court accepted an argument that the aboriginal artist stood in a fiduciary relationship with the community. The Reasons for Judgment include an extensive discussion about the continuity of aboriginal customary laws respecting ownership and use of traditional knowledge and cultural property in Australian common law following the assertion of British sovereignty. These customary laws continued to be valid until they were displaced by the enactment of the *Copyright Act* in the early part of the 20th century.[173] Despite this, the Court was disposed to view aboriginal customary law as part of the factual matrix leading it to conclude that the relationship between the aboriginal artist and the community was one of mutual trust and confidence, a relationship Australian law recognizes as a fiduciary relationship, with accompanying obligations. The Court noted that if a person in such a fiduciary relationship failed to take reasonable steps to enforce copyright in a work of art based on traditional knowledge, the community concerned would have a legal basis for a claim against the artist.[174]

---

[168] Christie, *supra* note 29, at para. 93.

[169] *Ibid.*

[170] *Indigenous Flora and Fauna & Maori Intellectual Property Claim, Wai 262.* The claim is before the Waitangi Tribunal in New Zealand, a commission of inquiry that was established in 1975 by the *Treaty of Waitangi Act* to consider claims by Maori based on the Treaty, which was signed by the Maori and representatives of the British Crown in 1840. The Tribunal is currently at the stage of writing a statement of issues for the claim, according to the Tribunal website. (See http://www.waitangi-tribunal.govt.nz/inquiries/current', last viewed April 1, 2004) Briefly, the claimants use rivers in Hawkes Bay - where farming and crops have progressively lowered the water table - as an example to explain the loss of indigenous knowledge and identity. At one level the river is a habitat for fish and eels. When the river floods, it waters the native plants on its banks. Tampering with the river affects the knowledge associated with the habitat. If the eels die, the knowledge of how and where to catch them is lost. If the flax that grows on the bank is affected, the knowledge of weaving cannot be passed on. The claimants argue that all of this affects the identity of the people. The claim also looks at legislation and how it has regulated the way in which Maori interact with society, and the way that their traditions have come under attack - such as the *Tohunga Suppression Act* of 1907 which banned traditional healers from practicing. The claimants argue that a consequence was the loss of traditional medicinal knowledge.

[171] *Bulun Bulun & Anor v. R & T Textiles Pty Ltd* [1998] 1082 FCA (3 September 1998). Another Australian case of interest is *Milpurrurru v. Indofurn Pty Ltd.*, (1994) 54 FCR 240, which established that aboriginal customary law could be used in the determination of damages for breach of copyright. For a brief discussion, see M. Blakeney, "Protecting Expressions of Aboriginal Folklore under Copyright Law, 1995, available at http://www.murdoch.edu.au/elaw/issues/v2n1/blakeney21.html, last viewed on March 4, 2004.

[172] The concept of aboriginal communal title under Australian law is discussed in *Mabo v. The State of Queensland* [No.2] (1992) 175 C.L.R. 1.

In drawing upon comparative examples, it is important to bear in mind that Canadian law is significantly distinct from the law of its commonwealth confrères in the South Pacific in that existing aboriginal rights are recognized and affirmed in the Constitution, which carries with it a host of implications respecting government conduct that are not present elsewhere. Nevertheless, these examples illustrate that claims related to TK could have broad impacts and implications, as suggested by the New Zealand Wai 262 claim, and that a certain amount of creativity on the part of litigants and judges may be called for to address them, as suggested by the copyright cases from Australia.

(ii) Self-Government and Land Claim Settlements

As noted above, the Supreme Court of Canada has encouraged the Crown to resolve aboriginal rights issues through negotiations rather than litigation, given the complexity of competing interests at stake. A variety of agreements are now routinely negotiated between aboriginal groups, governments and companies, from comprehensive land claim and self-government agreements such as those with the Nisga'a and Tlicho, to interim resource co-management agreements, impact benefit agreements, environmental agreements and others. Indeed, in a submission it made in relation to a case before the Inter-American Court of Human Rights, the Assembly of First Nations describes this approach as something of a model for countries that wish to support resource development projects on the traditional lands of indigenous peoples.[175] Some communities are also negotiating traditional knowledge access agreements with researchers, although legal requirements to do so do not exist under Canadian law, leaving these matters up to communities and researchers to address. Such agreements are also sometimes negotiated in the context of certain statutory requirements, as a few statutes in Canada require consideration of relevant traditional knowledge, although they do not establish requirements as to how such knowledge should be obtained.[176]

Canada's land claim and self-government negotiations are guided by its *Comprehensive Land Claims Policy* and *Aboriginal Self-Government Policy*, respectively. Traditional knowledge arises in relation to both of these processes.

In relation to land claims, traditional knowledge arises in a variety of ways, some of them indirect. For example, article 16.6.17 of the 1993 *Council of Yukon Indians Umbrella Final Agreement*, which forms the template for individual final agreements with Yukon First Nations, describes an obligation for Yukon First Nations to provide Renewable Resource Councils with information relevant to the board's functions concerning fish and wildlife, which could include traditional knowledge. This is a reasonable inference to be drawn from the article when it is read within the meaning of the objectives of Chapter 16, which clearly indicate that it is the intention of the parties to incorporate traditional knowledge in Council decision making.[177] Similarly, article 12.1.6 of the *Tlicho Agreement* provides that in exercising their powers under chapter 12, the parties and the renewable resources board established under the agreement "shall take steps to acquire and use traditional knowledge as well as other types of scientific information and expert opinion."[178]

---

[173] *Bulun Bulun*, *supra* note 171, at 21.

[174] *Ibid.*, at 29.

[175] P. Macklem and E. Morgan, "Indigenous Rights in the Inter-American System: The Amicus Brief of the Assembly of First Nations in Awas Tingni v. Republic of Nicaragua", 22 *Human Rights Quarterly* 569 (2000).

[176] See Christie, supra note 29; Kaska Nation, *Development of a Traditional Knowledge Protocol — From Concept to Best Practice*, copy on file; Council of Yukon First Nations, *Traditional Knowledge Research Guidelines*, 2000, available at: http://www.contaminants.ca/done/tkGuidelines/TK%20Guidelines.pdf, last viewed March 31, 2004; Namgis First Nation, *Guidelines for Visiting Researchers/Access to Information*, copy on file; Inuit Tapirisat of Canada, *Principles Regarding Research in the North*, available at http://www.users.ox.ac.uk/-wgtrr/inuit.htm, last viewed November 18, 2003; and K. Bannister, "Use of Traditional Knowledge of Aboriginal Peoples for University Research: An Analysis of Academic Ethics and Research Policies in British Columbia, Canada", May 2003, submitted to the Biodiversity Convention Office, Environment Canada, copy on file.

[177] *Umbrella Final Agreement*, 1993, Chapter 16, available at: http://www.ainc-inac.gc.ca/pr/agr/index_e.html, last viewed April 1, 2004.

Certain legislation enacted to give effect to land claims commitments, such as the *Yukon Environmental and Socio-Economic Assessment Act*, contain references to the inclusion of relevant traditional knowledge in decision making respecting land use issues. While references to traditional knowledge in relation to land and natural resource co-management matters does not mean that rights to TK are being recognized, it does suggest that the close relationship between TK and aboriginal land use is acknowledged by the parties involved. Aboriginal groups that are concerned about the impact of references to traditional knowledge in land claims agreements, particularly in relation to provisions like article 16.6.7 of the UFA, which create knowledge disclosure obligations for First Nations, may wish to elevate the discussion to the level of rights, and argue that protections are required in return for commitments to share certain knowledge.

Further, land claims agreements typically involve the transfer of some Crown lands to the aboriginal community involved as "fee simple" settlement land. These lands are held collectively by the community, which exercises most of the rights of a private property owner, including with respect to the control of access to the lands, subject to the terms of the applicable land claim agreement, and to laws of general application. This means that aboriginal communities that have entered into land claim agreements will have the capacity, albeit not unfettered, to control bioprospecting on their lands.[179] Outside of the context of comprehensive land claims, communities that are Indian bands under the *Indian Act* with reserve lands will also have an ability to exercise some control over access to biological resources on reserve, although the Crown is actually the owner of reserve lands, which it holds for the exclusive use and benefit of the bands.[180]

Traditional knowledge is also important in self-government negotiations. As a matter of policy, the Government of Canada has recognized the inherent right of self-government as an existing aboriginal right under section 35, to be exercised on the basis of negotiated agreements operating within the framework of the Canadian Constitution. The *Aboriginal Self-Government Policy* states:

> Recognition of the inherent right is based on the view that the Aboriginal peoples of Canada have the right to govern themselves in relation to matters that are internal to their communities, integral to their unique cultures, identities, traditions, languages and institutions, and with respect to their special relationship to their land and their resources.[181]

The Policy establishes three categories of matters. The first, which includes the establishment of governing structures, aboriginal language, culture and religion, administration of aboriginal laws, natural resource management, and others, is regarded as a list of possible subjects for negotiation leading to the recognition of aboriginal jurisdiction and law making authority over these matters. The second includes matters over which aboriginal governments might be granted a level of authority subordinate to federal or provincial authority. The third includes those matters over which it is essential that the federal government retain its law making authority.[182]

Noteworthy from the perspective of traditional knowledge issues, federal powers respecting intellectual property are included in the third category list, while aboriginal culture is included in the first. The result is that aboriginal governments may have the power to make laws respecting aboriginal culture, but not respecting the federal power over intellectual property matters.[183] As a result, challenging relationship of laws issues could arise. Due to the transnational nature of intellectual property matters, such issues could ultimately feature domestic law and both private and public international law dimensions.

---

[178] *Tlicho Agreement*, 2003, Chapter 12, available at: http://www.ainc-inac.gc.ca/pr/agr/index_e.html, last viewed April 1, 2004.

[179] Land claims agreements typically make reference to fee simple settlement lands and to settlement areas. Fee simple settlement lands are lands that the aboriginal group receives fee simple title to – that is, the lands they own pursuant to the settlement agreement. Fee simple settlement lands amount to a portion of the total settlement area. In some cases, the aboriginal group may receive title to the subsurface resources that lie beneath some or all of their fee simple settlement lands. The "settlement area" is the total area covered by the agreement. Generally this area reflects the traditional use patterns of the aboriginal group. The group will have certain rights as specified in the agreement in the total settlement area, such as certain hunting and fishing priority rights, along with certain co-management opportunities.

[180] Indian bands have some by-law making authorities under the *Indian Act* R.S. 1985, c.I-5 that may be relevant to access issues. In practice, they may assert and exercise additional powers.

[181] Self-Government Policy, *supra* note 137, at 3.

[182] *Ibid*, at 5 to 7.

Although traditional knowledge is not specifically mentioned in the *Aboriginal Self-Government Policy* lists, it is fair to assume that it is closely connected to aboriginal "language, culture and religion", which is a list one item for purposes of negotiation.[184] Accordingly, it is one of the areas that Government views as "internal to the group, integral to its distinct aboriginal culture, and essential to its operation as a government or institution."[185]

(iii) Individual versus Collective Rights Issues

Due to the nature of traditional knowledge, which is regarded as a collective rather than individual good, the focus of this section has been on collective aboriginal and treaty rights. As indicated above, an overview of the domestic human rights law framework is provided in chapter one of the paper. As was the case in relation to the discussion of international law and "TK rights", however, it is important to note that conflicts might arise between any aboriginal right to control traditional knowledge that might be found to exist, and individual human rights set out in the *Canadian Charter of Rights and Freedoms*.

Chapter one identified a few Charter rights that could conceivably be engaged in the context of biotechnology. Two of these are the "right to life, liberty and security of the person" and the right to equality in sections 7 and 15, respectively, of the Charter. It is not clear whether or how these Charter rights could arise in relation to conflicts between , for example, an aboriginal community's interest in protecting and controlling traditional knowledge and the rights of an individual member of a community or individual non-aboriginal person. For discussion purposes, it can be speculated that perhaps a situation could arise in which individuals would benefit from knowledge that a community does not wish to disclose.

Assuming that the Charter applies to such a situation,[186] and that the aboriginal community is acting on the basis of an existing aboriginal or treaty right, the question of the interpretation of section 25 of the *Constitution Act, 1982* might arise. Section 25 addresses the relationship between aboriginal and treaty rights recognized and affirmed by section 35 and the rights of individuals guaranteed by the Charter. It provides:

> The guarantee in the Charter of certain rights and freedoms shall not be construed so as to abrogate or derogate from any aboriginal, treaty or other rights or freedoms that pertain to the aboriginal peoples of Canada including
>
> a. any rights or freedoms that have been recognized by the Royal Proclamation of October 7, 1963; and
>
> b. any rights or freedoms that now exist by way of land claims agreements or may be so acquired.

The section has not yet been interpreted in a determinative way by the courts, but could play some sort of shielding or balancing function in resolving conflicts between aboriginal and individual rights.[187] For the purposes of this chapter, it is simply mentioned here as a relevant feature of the domestic rights framework that is likely to play an increasingly prominent role over time in litigation respecting the relationship between aboriginal rights and Charter rights, particularly with the negotiation and implementation of more self-government agreements.[188]

---

[183] *Nisga'a Final Agreement*, Chapter 11, Articles 41 to 42. Available at http://www.ainc-inac.gc.ca, last viewed April 1, 2004. Article 41 states: "Nisga'a Lisims Government may make laws to preserve, promote, and develop Nisga'a culture and Nisga'a language, including laws to authorize or accredit the use, reproduction, and representation of Nisga'a cultural symbols and practices, and the teaching of Nisga'a language." Pursuant to s. 91 of the *Constitution Act, 1867*, the exclusive legislative authority of the Parliament of Canada extends to all matters coming within certain classes of subjects, including "Patents of Invention and Discovery" and "Copyrights".

[184] The meaning of the word "culture" is hard to define. In the *Universal Declaration on Cultural Diversity*, the members of UNESCO state that culture "should be regarded as the set of distinctive spiritual, material, intellectual and emotional features of society or a social group, and … encompasses in addition to art and literature, lifestyles, ways of living together, value systems, traditions and beliefs." (*Supra* note 48, preamble para. 5).

[185] Self-Government Policy, supra note 137, at 5.

[186] Pursuant to s. 32(1) of the *Constitution Act, 1982*, the Charter applies to "the Parliament and government of Canada in respect of all matters within the authority of Parliament…" and "to the legislature and government of each province in respect of all matters within the authority of the legislature of each province". The Charter also applies to aboriginal governments exercising authorities delegated to them by Parliament. Self-government agreements include provisions reinforcing that the Charter applies to self-governing aboriginal groups.

[187] Arbour, *supra* note 40.

D. Summary

There is no case law in Canada confirming that aboriginal people as a whole, or any particular aboriginal group in particular, has a right to own and control traditional knowledge. As indicated above, Canadian case law has developed in such a way that it is capable of addressing the latter issue – the rights of particular aboriginal groups on a case by case basis – rather than the former – the rights of all of the aboriginal peoples of Canada as a whole. However, a few general comments can be made that may provide guidance to policy makers working in the field of biotechnology.

Tests have been developed by Canadian courts to assess in which circumstances aboriginal and treaty rights exist, such that they are subject to the protections provided by section 35 of the *Constitution Act, 1982*. These tests focus on those practices, traditions and customs of an aboriginal group that have continuity with those that were exercised prior to European contact and that are integral to its distinctive culture. Although litigation respecting the assessment of the existence of unextinguished aboriginal rights tend to have focused to date on such topics as title to lands and the ability of a group to continue to carry out some sort of tradition based activity, such as hunting, fishing or trapping, there is nothing in the case law to suggest that questions about an aboriginal right to own and control traditional knowledge could not be tested through the courts. However, at this point it is purely a matter of speculation whether litigation would result in a determination that such rights exist.

There are two general principles that can be drawn from the discussion above: (1) aboriginal and treaty rights analysis under Canadian law is not about absolutes – it is about balancing competing interests within the scope of the framework established by the Constitution and by the common law, but on the basis that in arriving at the appropriate balance, the fiduciary relationship that exists between the Crown and aboriginal peoples must always be respected; and (2) this is often better done by engaging in contextual negotiations and consultations that address the interests of all parties concerned, rather than resorting to the blunt tool of litigation.

Although no court has held that an aboriginal right to own and control traditional knowledge exists under Canadian law, government is always well advised to consider whether its activities could infringe aboriginal rights that may be found to exist, along with those that have already been established through case law, land claim or self-government agreement, or statute. A consultative approach can often help avoid unnecessary litigation and lead instead to results that are satisfactory to all parties involved. Consultation may be an appropriate tool to turn to at any stage in the process of addressing biotechnology issues relevant to aboriginal people and their TK, including policy development, where aboriginal representatives could be specifically invited to participate in the process of obtaining input from interested parties, to the development of legislation, to the design of particular activities. Regardless of whether an applicable rights determination is ever made, in matters related to TK, aboriginal input is clearly desirable.

Finally, policy makers in the field of biotechnology should be sensitive to the link that exists between traditional knowledge access and ownership issues and the provisions of land claim and self-government agreements.

7.5 Options to "Respect, Preserve and Maintain" TK

This chapter is not about intellectual property law or policy and does not identify or compare all of the options that may be available for the protection of TK, or to address "TK rights". However, it is useful to identify some of the available mechanisms. In this section, the rights discussion is therefore momentarily set aside.

Tools for the protection of traditional knowledge have been identified in a host of materials available elsewhere. The protection of traditional knowledge through intellectual property laws or *sui generis* laws and policies specifically addressing indigenous knowledge is being addressed by WIPO and has been considered by a number of commentators.[189] Further work on this topic will also be undertaken by the CBD Working Group on Article 8j.[190]

---

[188] Also of interest in relation to the relationship between collective and individual rights, s. 35(4) of the *Constitution Act, 1982* states: "Notwithstanding any other provision of this Act, the aboriginal and treaty rights [recognized and affirmed pursuant to] subsection (1) are guaranteed equally to male and female persons."

Meanwhile, some countries are developing policies respecting access to genetic resources and benefit sharing in relation to their utilization that will have to address indigenous interests (Canada and New Zealand, for example) or have already completed such a law and policy-making process (Australia).[191] Other countries have enacted laws regulating the protection of traditional knowledge[192], or, in Canada, addressing the use of traditional knowledge in legislation regulating environmental assessments and land use decision making.[193] Indigenous communities have also developed best practice guidelines for the utilization of traditional knowledge, subject to their prior informed consent, that are available to policy makers.[194] In addition, WIPO is researching how indigenous customary laws and practices might be respected in relation to access to and use of TK, along with a number of Canadian commentators.[195]

Accordingly, a body of materials exists that can be mined for ideas as to how to deal with issues about access to, and the utilization of, traditional knowledge. The existence of this body of materials suggests that there is a level of recognition that indigenous peoples' interests in TK should be respected and that steps should be taken to promote benefit sharing with indigenous communities when their TK is utilized, principles that reflect those found in Article 8j of the CBD.

Many available mechanisms that are available to assist indigenous people to control when and how traditional knowledge is used have significant shortcomings. As has been mentioned elsewhere in the chapter, although existing intellectual property law tools can sometimes be used to protect traditional knowledge, they are significantly limited in this regard because, for example, they can be prohibitively expensive to use, traditional knowledge is often publicly available and indigenous peoples claim immemorial ownership of traditional knowledge rather than time limited interests in it. The international community appears to be poised to more actively seek ways to address these problems, which have implications for Canadian law and policy making in this field. Further, simply mentioning traditional knowledge in certain pieces of legislation without considering impacts from a rights-based perspective can raise problems. For example, in Canada once traditional knowledge is used for the purposes of environmental assessments, it may become available to the public as a result of the application of the *Access to Information Act*.[196]

---

[189] See WIPO documents, *Traditional Knowledge: Policy and Legal Options*, WIPO/GRTKF/IC/6/4, *Elements of a Sui Generis System for the Protection of Traditional Knowledge*, WIPO/GRTKF/IC/4/8 and *Comparative Summary of Existing Sui Generis Measures and Laws for the Protection of Traditional Knowledge*, WIPO/GRTKF/IC/5/INF/4. For commentary on the issues, see: M. Denhez, "Protecting Traditional Cultural Expression: The Existing Canadian Toolkit", unpublished, copy on file; H. Mann, *Indigenous Peoples and the Use of Intellectual Property Rights in Canada*, prepared for Industry Canada, available at: http://www.nativemaps.org/abstracts/indigenous_people.pdf, last viewed March 31, 2004; Department of Indian Affairs and Northern Development and Industry Canada, *Intellectual Property and Aboriginal People: A Working Paper*, 1999; A. Gupta, "Rewarding Conservation of Biological and Genetic Resources and Associated Traditional Knowledge and Contemporary Grassroots Creativity", Indian Institute of Management Ahmedabad Working Papers, 2003, available at: http://netec.wustl.edu/WoPEc/data/Papers/iimiimawp2003-01-06.html, last viewed March 31, 2004; Downes, *supra* note 22; and Correa, *supra* note 25.

[190] See UNEP/CBD/COP/7/L.19/Rev1, item H, "*Development of elements of sui generis systems for the protection of traditional knowledge, innovations and practices*". Available at http://www.biodiv.org, last viewed April 1, 2004.

[191] For a description of the Australian approach to the regulation of access and benefit sharing, see Commonwealth Public Inquiry, *Access to Biological Resources in Commonwelath Araes*, 2000; and the power point presentation by the Director of the Australian office responsible for access and benefit sharing: http://www.med.govt.nz/ers/nat-res/bioprospecting/seminar-20030221/burton/burton-slides.ppt, last viewed March 31, 2004. For links to actual or proposed laws regulating access to genetic resources in other countries see the website of the Environmental Law Alliance Worldwide: http://www.elaw.org/resources/topical.asp?topic=Access+to+Genetic+Resources, last viewed March 31, 2004.

[192] See WIPO document, *Comparative Summary of Existing Sui Generis Measures and Law for the Protection of Traditional Knowledge*, WIPO/GRTKF/IC/5/INF/4.

[193] *Supra* note 129.

[194] *Supra* note 174.

[195] See WIPO documents, *Traditional Knowledge: Policy and Legal Options*, WIPO/GRTKF/IC/6/4, *Elements of a Sui Generis System for the Protection of Traditional Knowledge*, WIPO/GRTKF/IC/4/8 and *Comparative Summary of Existing Sui Generis Measures and Laws for the Protection of Traditional Knowledge*, WIPO/GRTKF/IC/5/INF/4. For commentary on the role of customary laws in Canadian common law generally, see, for example, Borrows, *supra* note 16 and Sakej Henderson, "Empowering Treaty Federalism" (1994) 58 Sask. L. Rev. 241. For a historical perspective, see M. Walters, "Mohegan Indians v. Connecticut (1705-1773) and the Legal Status of Aboriginal Customary Laws and Government in British North America", (1995) 33 Osgoode Hall L.J. 785.

[196] The *Access to Information Act*, R.S. 1985, c. A-1, includes some exceptions to the kinds of information that must be disclosed with government files upon a request made by a member of the public in accordance with the Act. For example, commercial information from a private company is excluded. Traditional knowledge is not.

It is also questionable whether an aboriginal group should be required to disclose TK, which appears to be the case, for example, under certain land claims agreements as described above, although such requirements are found in negotiated settlements with the consent of all the parties to them. Finally, it may not be enough to leave the issue of access to TK to aboriginal people to regulate alone through the negotiation of "TK contracts" with researchers and others. If there is a valid rights dimension to TK, additional protective measures may be required that involve recourse to enforcement mechanisms operated by the State in cases of misappropriation.

The identification of options to "respect, preserve and maintain" traditional knowledge with a view to a rights perspective raises once again the issue of balance, that was mentioned in the first paragraph of this chapter. The appropriate balance to target in efforts to reconcile indigenous interests with other public policy considerations respecting the wide dissemination and use of all sources of knowledge that carries social benefits is a fundamental issue in discussion about the relationship between biotechnology and TK. Borrows has suggested that indigenous customary laws and practices respecting the utilization of traditional knowledge might be usefully assessed as a source of principles upon which to undertake this reconciliation.[197]

The relationship between customary laws and protocols and access to traditional knowledge is a topic of debate internationally.[198] Many countries have experience integrating indigenous law with Western legal traditions.[199] Indeed, indigenous law respecting land ownership played an important role in a recent indigenous rights decision of the Constitutional Court of South Africa.[200] With respect to the Canadian context, Mark Walters has suggested that the "... challenge of defining aboriginal rights stems from the fact that they are rights peculiar to the meeting of two vastly different legal cultures; consequently there will always be a question about which legal culture is to provide the vantage point from which rights are to be defined... a morally and politically defensible conception of rights will incorporate both legal perspectives."[201] In response to this notion, Lamer C.J. has stated that in considering a claim for the existence of an aboriginal right,

> ... a court must take into account the perspective of the aboriginal people claiming the right...It must also be recognized, however, that that perspective must be framed in terms cognizable to the Canadian legal and constitutional structure. As has already been noted, one of the fundamental purposes of s. 35(1) is the reconciliation of the pre-existence of distinctive aboriginal societies with the assertion of Crown sovereignty. Courts adjudicating aboriginal rights claims must, therefore, be sensitive to the aboriginal perspective, but they must also be aware that aboriginal rights exist within the general legal system of Canada.[202]

Pressure to find ways to incorporate customary laws and practices into Canadian common law are likely to increase over time, particularly if the breadth of the discussion expands to include laws enacted by self-governing aboriginal communities. In this regard, it may be preferable to use the broader term "indigenous laws" rather than "customary laws".

---

[197] Personal communication with J. Borrows, March 19, 2004, copy of written comments of Borrows to this effect on file. Borrows argues that the aboriginal rights analysis found in Canadian case law is conducive to recognition of customary laws and protocols. For example, aboriginal customary law respecting adoption was given recognition by the B.C. Court of Appeal in its 1993 decision in *Casimel v. Insurance Corporation of British Columbia*, available at: http://www.courts.gov.bc.ca/jdb-txt/ca/93/05/c93-0563.htm, last viewed March 17, 2004. Besides the question of the status of aboriginal customary laws in Canadian common law, Borrows suggests that aboriginal concepts about justice and balance can be drawn upon to inform the balancing that may be required between the interests of aboriginal people and Canadian society as a whole. Also see Borrows, *supra* note 16.

[198] The WIPO IGC is addressing questions about the relationship between customary laws and practices and the protection of traditional knowledge through intellectual property or *sui generis* approaches. See, for example, the WIPO Secretariat's publication, Traditional Knowledge: Policy and Legal Options, WIPO/GRTKF/IC/6/4. Available at www.wipo.org, last viewed March 15, 2004.

[199] For an Australian example, see *Bulun Bulun, supra* note 169. For one from New Zealand, see *Bioprospecting in New Zealand: Discussing the Options*, Ministry of Economic Development, available at http://www.med.govt.nz/ers/nat-res/bioprospecting/discussion/bioprospecting-07.html, last viewed October 7, 2003 or New Zealand Law Commission Study Paper 9, Maori Custom and Values in New Zealand Law, 2001, available at http://www.lawcom.govt.nz, last viewed March 31, 2004.

[200] *Richtersveld Community and Others v. Alexkor Ltd. and Another* 2001 (3) SA 1293 (LCC), available at: http://www.concourt.gov.za/files/alexkor/alexkor.pdf, last viewed March 31, 2004.

[201] M. Walters, "British Imperial Constitutional Law and Aboriginal Rights: A Comment on *Delgamuukw v. British Columbia*" (1992) 17 *Queen's L.J.* 350, at 412 to 13.

[202] *Van der Peet*, supra note 153, at para. 49.

The diversity of aboriginal customary laws and practices makes assessing whether they offer useful principles to assist in finding an appropriate balance between the interests of aboriginal people in TK and other policy considerations a truly daunting task. On the other hand, a more modest but very important implication of Borrow's suggestion may provide the basis for a practical starting point: in matters related to TK, a better understanding of indigenous interests, understandings and perspectives is critical. In order to achieve this, indigenous people should be given opportunities to participate in policy making respecting traditional knowledge and to provide guidance in the development of options to address their interests.

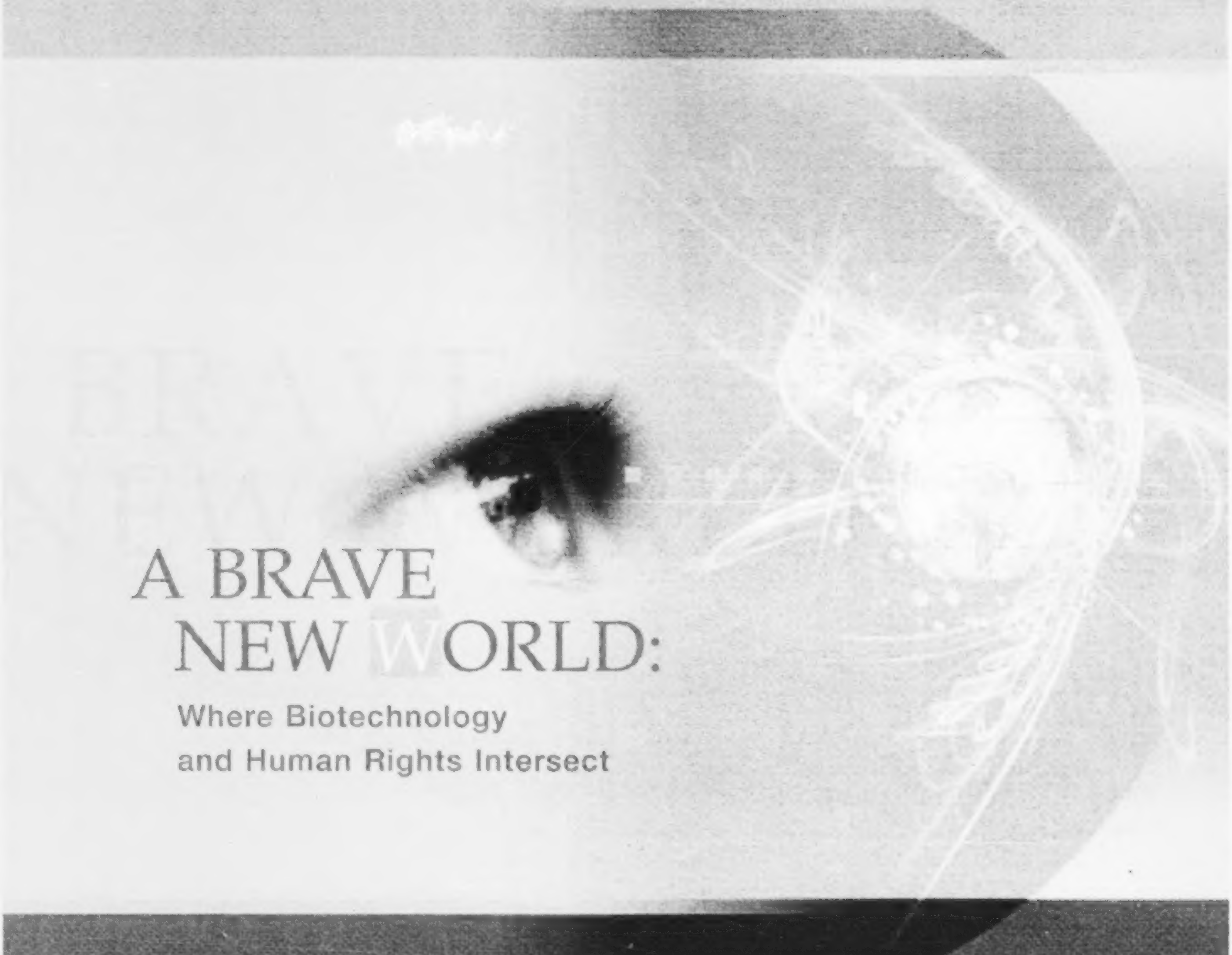
7.6 Conclusion

The interest that the biotechnology industry and governments that support it share with indigenous peoples in biological resources and traditional knowledge about its applications both poses challenges for all parties, and creates some opportunities. A satisfactory approach to this situation may be one that permits the utilization of such resources and knowledge for the benefit of everyone, but recognizes that indigenous people's interests in them must be respected. Society at large shares a common interest in supporting the economic, cultural, social and political development of indigenous peoples. While this statement can be supported on the basis of a host of reasons, it is reinforced by the bedrock of rights.

This chapter suggests that a specific indigenous right to own and control traditional knowledge is not yet recognized under international or Canadian law. However, such a right, or something like it, might be given shape internationally with continued efforts to consider and address indigenous peoples' issues in various fora, including the CBD, WIPO and the Working Group on the Draft Declaration. It might also be given some expression under Canadian law or through the medium of self-government and land claim negotiations and agreements.

However, even now a fundamental principle is present at the international and domestic levels. This principle is sometimes but not always connected with a legal obligation. For example, it can be found in Human Rights Committee opinions respecting complaints about alleged violations of Article 27 of the ICCPR and in Canadian case law addressing certain specific fact situations. More often, it simply makes good policy sense, reflected in decisions by States to include indigenous representatives in international negotiation processes about matters that concern them, or in decisions by governments in Canada to seek indigenous views about a host of topics. Indigenous people should be given opportunities to play a central role in law and policy making about issues that are of importance to them, including issues respecting the utilization of traditional knowledge in biotechnology research. Making a final determination that an indigenous right to control TK is well established in law is not a necessary requirement before such a principle can be embraced and implemented.

Government of Canada Gouvernement du Canada



A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Conclusion and Glossary

Canada

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

PERMISSION TO REPRODUCE

Except as otherwise specifically noted, the information in this publication may be reproduced, in part or in whole and by any means, without charge or further permission from the Government of Canada, provided that due diligence is exercised in ensuring the accuracy of the information reproduced; that the Government of Canada is identified as the source institution; and that the reproduction is not represented as an official version of the information reproduced, nor as having been made in affiliation with, or with the endorsement of, the Government of Canada.

For permission to reproduce the information in this publication for commercial redistribution, please e-mail: copyright.droitdauteur@communication.gc.ca.

Cat. No. Iu199-6/2005E-PDF
ISBN 0-662-41902-2

Also available in electronic format on the Internet at:
http://biotech.gc.ca

Conclusion

The purpose of this project has been to examine select applications of biotechnology within the framework of human rights and identify any gaps in rights protection. The project examined biotechnology, jurisprudence and legislation at a particular point in time. Advances in biotechnology occur at such a rapid pace that there may have been significant developments since the time of writing that are not reflected in the chapters.

In many cases, the authors attempted to look to the future and speculate as to what situations might arise as a result of advances in biotechnology. This meant that many of the issues that arose were novel and it was difficult to determine how the courts might address them. The goal at the start of the project was to devise a human rights framework for the application of biotechnology. It soon became apparent that a single framework could not be developed that would address the diverse applications of biotechnology and the spectrum of human rights issues that arose.

The application of biotechnology often raises difficult moral and ethical issues, as well as novel legal issues. The United Nations ("U.N.") human rights instruments are of limited guidance. This is not surprising considering the difficulties of reaching international consensus on many of the human rights issues raised by biotechnology. The U.N. treaties provide only a basic minimum of guidance in terms of rights protection in this area. Many of the issues raised by biotechnology are multi-dimensional and value laden, and as such, the task of achieving consensus between states on the wording of an international treaty addressing these issues would be extremely difficult. The courts may find more guidance from UNESCO declarations that, while of a non-binding nature, offer more concrete guidance on these issues.

In Canada, the *Charter* provides protection for rights and freedoms in the event of government action or interference. The most oft engaged *Charter* rights with respect to assisted human reproduction technologies would be those found in section 7. The lack of jurisprudence in this area will present challenges to the courts. In addition, the status of the *in vitro* embryo and whether it possesses any rights is an issue that has not yet been addressed by the courts. The issues outlined in Chapter 7 relating to indigenous peoples and possible rights to protect and use their traditional knowledge have not yet come before the courts in Canada. The courts may be forced to craft novel solutions to these difficult issues.

Waiting for the judiciary to provide guidance is always a slow and often unsatisfactory approach. The gaps that emerge from the review and analysis may be best addressed through a variety of mechanisms ranging from legislative provisions to regulations to codes of practice, rather than through amendments to human rights legislation. Canada should consider whether to proactively address gaps in human rights protection through appropriate mechanisms rather than waiting for the courts to decide these matters.

Not every application of biotechnology was examined. For example, the creation of genetically modified foods, nanotechnology and pharmacogenetics were not explored. However, that does not mean that these matters are unimportant and should not be the focus of future work. The technologies likely raise novel ethical and legal issues, and likely raise human rights issues, that should be considered. Furthermore, not all of the applications of assisted human reproduction were explored. The issues relating to surrogacy motherhood and as well, other questions relating to the application of assisted reproduction technologies were not examined. The following questions were not addressed: Do children have a right to have two biological parents of the opposite sex? Does a child have a right to have a "normal" or "natural" genetic origin? Do parents have the right to have a child conceived using their own genetic material, even if this means using the genetic material from three biological parents?

A major issue that was not explored regarding indigenous rights and traditional knowledge relates to the fact that indigenous communities are sometimes viewed as a good source of raw materials for human genetic research since they often represent a homogenous gene pool. Indigenous peoples have expressed concerns that they may be targeted for discrimination during or as a result of such research. One such concern relates to the possibility that the results of such research may be used to determine who is a member of a particular indigenous community.

This project began by examining human rights issues of an intensely personal and private nature that may arise in the area of human reproduction and ended with an examination of issues of a "collective" nature. It is clear that not every application of biotechnology is best addressed through a human rights framework. The project papers illustrate, however, that certain applications of biotechnology raise human rights issues that could be addressed through legislative amendment or regulation. Protecting individual rights and the interests of collectives would help to ensure that society as a whole continues to benefit from responsible scientific progress.

Glossary

A

AHR

assisted human reproduction

artificial insemination (AI)

The introduction of semen into the vagina other than by coitus.

azoospermia

Absence of living sperm in the semen.

B

BRCA1 gene

A tumor suppressor gene on chromosome 17 at locus 17q21, isolated in 1994; encodes p53 protein, which prevents cells with damaged DNA from dividing; carriers of germline mutations in BRCA1 are predisposed to develop both breast and ovarian cancer.

BRAC2 gene

A tumor suppressor gene indentified in 1995 on chromosome 13 at locus 13q12-q13; a large gene; encoding a protein of 3418 amino acids; carriers of germline mutations in BRCA2 have an increased risk of developing breast cancer and a moderately increased risk of ovarian cancer; BRCA2 families also exhibit an increased incidence of male breast, pancreatic, prostate, laryngeal, and ocular cancers.

blastocyst

An early pre-implantation embryo which consists of an inner and an outer cell layer surrounding a fluid-filled central cavity. The surface cells will give rise to extra-embryonic tissues, and the inner cells will become the fœtus.[1]

blastomere

One of the cells into which the egg divides after its fertilization.

C

CBD

Convention on Biological Diversity

CEDAW

Convention on the Elimination of All Forms of Discrimination Against Women

CERD

International Convention on the Elimination of All Forms of Racial Discrimination

CRC

Convention on the Rights of the Child

---

[1] Webster's Online Dictionary, online: http://www.websters-online-dictionary.org/definition/english/ga/gamete.html (date accessed: 25 March 2004).

cloning

1. Growing a colony of genetically identical cells or organisms *in vitro*.

2. Transplantation of a nucleus from a somatic cell to an ovum, which then develops into an embryo; many identical embryos can thus be generated by asexual reproduction.

D

donor insemination (DI)

Artificial insemination with semen from a donor who is not the woman's husband.

Medical indications for donor insemination include azoospermia, oligospermia or the presence of a genetic disease in the male partner's sperm.

E

ESHRE

European Society of Human Reproduction and Embryology

EPC

European Patent Convention

EPO

European Patent Office

embryo

In humans, the developing organism from conception until approximately the end of the second month; developmental stages from this time to birth are commonly designated as fœtal.

eugenics

1. Practices and policies, as of mate selection or of sterilization, that tend to better the innate qualities of progeny and human stock.

2. Practices and genetic counselling directed to anticipating genetic disability and disease.

F

fœtus

The product of conception from the end of the eighth month to the moment of birth.

G

gamete

A mature sexual reproductive cell having a single set of unpaired chromosomes.[2]

gamete intra-fallopian transfer (GIFT)

A method of treating infertility by removing eggs from a woman's ovaries, combining them with sperm from her partner or a donor in the laboratory, and placing the eggs and sperm together in one of her fallopian tubes, where fertilization can occur.[3]

gene

A functional unit of heredity that occupies a specific place on a chromosome, is capable of reproducing itself exactly at each cell division and directs the formation of an enzyme or other protein. As a functional unit, the gene consists of a discrete segment of a giant DNA molecule containing the purine (adenine and guanine) and pyrimidine (cytosine and thymine) bases in the correct sequence to code the sequence of amino acids of messenger-RNA formed on the chromosome with the gene acting as a template.

---

[2] Webster's Online Dictionary, online: http://www.websters-online-dictionary.org/definition/english/ga/gamete.html (date accessed: 25 March 2004).

[3] Hyperdictionary, online: http://www.hyperdictionary.com/medical/gamete+intrafallopian+transfer (date accessed: 25 March 2004).

germ cell

The sex cells – ovum or sperm cells.

H

Human Genome Project

The Human Genome Project is a global, collaborative, scientific effort consisting of a number of national and international programs that began in the mid-1980s with the objective of mapping and sequencing the entire human genome.[4]

I

IACHR

Inter-American Convention on Human Rights

ICCPR

International Covenant on Civil and Political Rights

ICESCR

International Covenant on Economic, Social and Cultural Rights

IGC

Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore

ILO

International Labour Organization

implantation

Attachment of the fertilized ovum (blastocyst) to the endometrium, and its subsequent embedding in the compact layer, occurring 6 or 7 days after fertilization of the ovum in humans.

intra-cytoplasmic sperm injection (ICSI)

A procedure in which a single sperm cell is injected into the ovum during *in vitro* fertilization.

in vitro

In an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture media.

***in vitro* fertilization (IVF)**

A process whereby (usually multiple) ova are placed in a medium to which sperm are added for fertilization, the zygote thus produced then being introduced into the uterus and allowed to develop to term.

O

OAS

Organization of American States

Oligospermia

A subnormal concentration of sperm in the penile ejaculate.

P

PIPEDA

Personal Information Protection and Electronic Documents Act

PGD

Pre-implantation genetic diagnosis. Genetic diagnosis performed on the *in vitro* embryo.

parthenogenesis

A form of nonsexual reproduction in which eggs are subjected to electrical shock or chemical treatment in order to initiate cell division and embryonic development.[5]

pluripotent cell

Primordial cells that may still differentiate into various specialized types of tissue elements.

---

[4] Allyn L. Taylor, "Globalization and Biotechnology: UNESO and an International Strategy to Advance Human Rights and Public Health" (1999) 25 Am. J. L. and Med. 479 at 5 (Lexis Nexis).

[5] The President's Council on Bioethics, "Human Cloning and Human Dignity: An Ethical Inquiry" (Washington, July 10, 2002) at 132 http://www.bioethics.gov/reports/cloningreport/fullreport-print.html.

S

somatic cell

The cells of an organism other than the germ cells.

somatic cell nuclear transfer

A process whereby the nucleus of a human egg is removed and replaced with the nucleus from a donor cell. The egg is artificially stimulated and it begins to develop as an *in vitro*.[6]

stem cell

1. Any precursor cell.

2. A cell whose daughter cells may differentiate into other cell types.

sterilization

The act or process by which an individual is rendered incapable of fertilization or reproduction.

T

TK

traditional knowledge

TRIPS

World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights

totipotent cell

An undifferentiated cell capable of developing into any type of body cell.

U

UDHR

Universal Declaration of Human Rights

UNCTAD

United Nations Conference on Trade and Development

UNESCO

United Nations Educational, Scientific and Cultural Organization

W

WHO

World Health Organization

WIPO

World Intellectual Property Organization

WTO

World Trade Organization

Z

zygote

The diploid cell resulting from union of a sperm and an ovum.

---

[6] *Ibid* PresidentÕs Council.